UNIVERSITY OF LIVERPOOL

Interventions to reduce psychological morbidities associated with infertility in Nigeria

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor of Philosophy

by

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DECLARATION

This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award. This thesis is being submitted in partial fulfilment of the requirements for the degree of PhD. This thesis is the result of my own independent work/investigation, except where otherwise stated. Other sources are acknowledged by explicit references. The views expressed are my own. I hereby give consent for my thesis, if accepted, to be available for photocopying and for interlibrary loan, and for the title and summary to be made available to outside organisations.

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LIST OF PUBLICATIONS

A. Papers published in peer-reviewed journals

1. **Aiyenigba, AO,** Weeks AD, and Rahman A (2019). Managing psychological trauma of infertility. African Journal of Reproductive Health, 23(2), pp.76-91.
2. **Aiyenigba AO**, Weeks AD (2017). Time to put women at the centre of decisions about infertility care. BMJ2017;356: i6815
3. **Aiyenigba AO** (2018) Fertility Life Counselling AID (FeLiCiA) - A Guiding Manual for Health Workers in Counselling Infertility Patients based on the Thinking Healthy Programme (THP). Available via open access at: https://doi.org/10.6084/m9.figshare.6729110.v1

B. Manuscripts under preparation

4. **Aiyenigba AO,** Weeks AD, Rahman A. A Feasibility Study of FELICIA, an intervention for the management of infertility induced psychological distress
5. **Aiyenigba AO.** Editorial: Historical Definitions of Infertility and the Burden of Disease on the African Woman

LIST OF ABBREVIATIONS

ART	Assisted Reproduction Technology
ASRM	American Society for Reproductive Medicine
BDI	Becks Depression Inventory
CIDI	Composite International Diagnostic Interview
CBT	Cognitive Behavioural Therapy
DSM-IV	Diagnostic & Statistical Manual, Fourth edition
DV	Domestic Violence
FELICIA	Fertility Life Counselling Aid
FHI	Family Health International
FSH	Follicle Stimulating Hormone
GHQ	General Health Questionnaire
GnRH	gonadotrophin-releasing hormone
HADS	Hospital Anxiety and Depression Scale
HIV	Human Immunodeficiency Virus
HPO	Hypothalamic-pituitary-ovarian
HSG	Hystero-salpingo-gram
ICMART	International Committee Monitoring Assisted Reproductive Technology
ICF	Informed Consent Forms
IPT	Inter Personal Therapy
IPV	Intimate Partner Violence
K6	6 item- Kessler Psychological Distress Scale
LH	Luteinizing Hormone
MAD	Mixed Anxiety and Depression
MAR	Medically Assisted Reproduction
LMIC	Low- & Middle-Income Countries
MDG	Millennium Developmental Goals
mhGAP	Mental Health Gap Action Programme
NARHS-Plus	National HIV & AIDS and Reproductive Health Survey Plus
NCCWCH	National Collaborating Centre for Women's and Children's Health

NICE	National Institute of Clinical Excellence
NHA	National Hospital Abuja
NVOG	Nederlandse Vereniging voor Obstetrie en Gynaecologie (Dutch Society for Obstetrics and Gynaecology)
PHQ	Patient Health Questionnaires
PID	Pelvic Inflammatory Disease
PIS	Participant Information Sheets
RCT	Randomised Controlled Trial
SAD	Seasonal Affective Disorders
SDG	Sustainable Developmental Goals
SFA	Seminal Fluid Analysis
SSA	Sub-Sahara Africa
STI	Sexually Transmitted Infection.
TEM	Tailored Expectant Management
THP	Think Healthy Programme
TTP	Time to Pregnancy
UCH	University College Hospital
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
USPSTF	United States Preventive Services Task Force
WHO	World Health Organisation

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Abstract

Introduction:

Infertility affects up to 30% of Sub Sahara Africa population. In African societies, having infertility can come with dire consequences, depending on the level of empowerment and the ability to resist infertility related stigma, leading to psychological distress, anxiety and depression for those affected.

Cognitive Behavioural Therapy (CBT) has been shown to be more effective than the pharmacological treatment of infertility-related depression (Faramarzi et al, 2008), therefore a need for the development of a culturally appropriated CBT based intervention for the management infertility-related psychological distress.

Objectives:

1. To determine the prevalence of psychological morbidities amongst infertility patients in 2 Nigerian hospitals
2. To develop and test Fertility Life Counselling Aid (FELICIA), an intervention for the management psychological morbidities associated with infertility
3. To understand patients' perspectives of the potential benefits of the FELICIA intervention, 6 weeks post intervention

Methods:

An intervention was developed using the MRC framework for development of complex health interventions (Craig et al, 2008). Research was carried out using mixed methods involving a cross-sectional survey, a feasibility study using external pilot randomised controlled trial, and qualitative research using semi structured one-to-one interviews.

Results:

FELICIA, a CBT based intervention was developed based on the WHO Thinking Healthy Programme to manage the psychological morbidities associated with infertility.

In a survey of 224 patients attending infertility clinics in 2 Nigerian cities, 96 patients (43%) had scores of 3 or more on the 12 item-GHQ, indicating psychological morbidity. High prevalence of psychological morbidity was recorded amongst patients with history of domestic violence, and a long-standing history of infertility treatment.

Participants were randomised into 2 groups for an external pilot randomised controlled trial to determine the feasibility of carrying out the FELICIA intervention within a busy clinical setting. Results showed those in the intervention group to have marked improvement, with 7 out of 8 returning to normal GHQ scores, compared to only 1 out of 8 participants in the control group (p value= 0.01; RR= 0.143; 95% CI 0.023 - 0.91). The estimated number needed to treat (NNT) for one additional patient to benefit is 1.33 patients. The results also provided parameters used to determine the sample size required to conduct a full randomised controlled trial.

Qualitative research findings suggest that the FELICIA intervention was well received by participants, who found the intervention to be empowering and beneficial in helping them manage infertility induced psychological distress.

Implications of Research:

Although infertility-related psychological distress remains highly prevalent amongst Nigerian infertility population, the development of a culturally appropriated counselling intervention, such as FELICIA, has the potential to reduce infertility related psychological distress, and can be conducted by clinic staff with minimal training.

Chapter 1:
Introduction

Infertility is a common condition affecting a significant population worldwide. The social and psychological consequences of having infertility are dependent on the cultural expectations and value placed on child bearing. In African societies, being infertile can come with dire consequences, depending on the level of empowerment and the ability to resist infertility-related stigma by those affected (Dhont et al, 2011). Being female, uneducated, and socioeconomically disempowered, increases the likelihood of infertility-related stigma and abuse as a result of childlessness (Dhont et al, 2011; Donkor & Sandall, 2007).

Many countries in the sub-Sahara region of Africa have a high prevalence of infertility and have been described as a part of the infertility belt (Mascarenhas et al, 2012). Despite the high prevalence of infertility, the global emphasis is upon policies that control fertility within this region. This is mainly because high levels of infertility coexist with high fertility rates. While family planning and fertility control initiatives are heavily subsidised and promoted, infertility management has been left behind to sustain itself, transferring the cost to the patient. This means that for the millions of people with infertility in Africa, finding a solution to childlessness, or the inability to get a desired pregnancy, comes at an inconveniently high cost. Despite great progress in the medical treatment of infertility through assisted reproductive techniques (ART), these treatments are inaccessible for many in low- and middle-income countries (LMIC), because of their high financial costs. In the majority of African societies, this is a source of psychological distress for the patients, further compounded by the sociocultural stigma of infertility as well as the physical demands of infertility treatment (Nachigall, 2006; Hammarberg & Kirkman, 2013).

Lately, there has been a shift in infertility policy development towards reducing cost regulation of infertility treatments, as well as subsidy initiatives to reduce the high cost of infertility treatment (Nachigall, 2006; Ombelet et al, 2008). A lot more needs to be done to reduce the challenges and psychological

distress faced by patients who are currently receiving infertility treatment. This research project examines the problem of infertility in the African context, with a focus on the psychological morbidities associated with it. The research uses a mixed methods approach to identify the extent of problem of infertility in African societies, as well as to develop and test a culturally appropriate intervention for the management of the psychological distress associated with infertility. The research methodologies and findings are described in detail in chapters 3 to 6. The implication of the research outcomes, as well as the future directions are discussed in chapter 7.

Description of Subsequent Chapters

Chapter 2

Chapter 2 is a literature review of infertility, the definitions and types of infertility, as well the psychological problems and interventions for the management of infertility-related distress. This chapter examines how the various aspects of infertility discourse contribute to the psychological experience of being affected by, and coping with infertility in African settings.

Chapter 3

Chapter 3 illustrates a cross-sectional survey to determine the prevalence of infertility-related psychological morbidities among infertility patients in 2 Nigerian hospitals. Nigeria was chosen as the research setting, first because Nigeria has a high infertility prevalence, lying within the infertility belt described by Mascarenhas[a] et al (2012). Also, the researcher is a Nigerian, and so she has insights into the people and culture of the research setting. This cross-sectional study served as a screening phase to identify those patients who experienced psychological distress and would be eligible to test the intervention developed in Chapter 4.

Chapter 4

This chapter describes the ideologies and processes behind the development of a culturally appropriate, holistic and community-oriented intervention for the management of infertility related psychological distress.

The intervention developed is called FELICIA (Fertility Life Counselling Aid), and based upon the WHO Thinking Healthy programme. The development process was based upon evidence from infertility research, whereby gaps in infertility psychological support and care were identified, and an evidence-based intervention was developed to tackle those unmet needs.

Chapter 5

Chapter 5 describes a feasibility study, to test the FELICIA intervention developed in chapter 4 on infertility patients who had been identified in chapter 3 as having infertility induced psychological distress. The feasibility study was carried out using an external pilot trial methodology. Participants were randomised into 2 groups; an intervention group and a no intervention (comparison) group. Outcomes were compared to determine the feasibility of the intervention for the management of infertility induced distressed within a Nigerian clinical setting.

Chapter 6

Chapter 6 describes the process and the findings of a qualitative research study, exploring the perceptions of the FELICIA programme among those who had taken part in the pilot study. The qualitative research used one-to-one interviews to understand patient perspectives regarding the intervention's benefits and challenges. The findings explained the patient outcomes identified in Chapter 5 in the intervention group, and suggested future improvements and direction for the FELICIA intervention as well as the management of infertility-induced psychological distress.

Chapter 7

This concluding chapter synthesises the findings of the mixed methods research project and addressed the resulting practical implications. It also assessed the future directions for FELICIA and psychological management of infertility, in terms of programme and research development. The overall strengths and limitations of the research project were also discussed in detail in this chapter.

Conclusion

This segment gives an overview of the research project, and suggests critical research questions regarding the infertility-related psychological effects and the interventions developed to manage them within a resource-limited African setting.

Chapter 2:
Infertility, Psychological Risks, Associated Morbidities and Interventions.

Introduction

Infertility is generally defined as the inability to achieve pregnancy after at least one year of regular unprotected sexual intercourse (Zegers-Hochschild et al, 2009; WHO, 2010). Infertility can be primary in couples who have never conceived or secondary in couples who have previously conceived (Monga & Dobbs, 2011). Defining infertility generally is difficult as different terms are synonymous with infertility but not exactly alike. Terms such as sterility, infecundity, childlessness, and subfertility are used interchangeably to describe infertility in the scientific literature to describe infertility without clarifications on what exactly these terms mean or what they measure (Mascarenhas et al[a], 2012).

Search Strategy for Literature Review:

A literature search was carried out by exploring multiple bibliographic electronic databases through the University of Liverpool online library which gives access to 506 scientific databases across all subjects. The databases include EBSCO Discovery Service, Scopus, Web of Science, MEDLINE, Science Direct, CINAHL, PsycINFO, PubMed, Project MUSE, ProQuest and PopLine. Google Scholar as well as targeted internet searching of institutional websites were used to identify additional sources of evidence in grey literature.

The literature review was initially carried out using the key words from the title of the thesis at two levels:

1. Infertility: '*infertility definition', 'epidemiology of infertility', 'infertility in Nigeria', 'infertility in Africa', 'social problems of infertility', 'cost of infertility', causes of infertility,* and *'infertility aetiology'.*
2. Psychological problems of infertility: '*infertility-related psychological distress', 'infertility AND anxiety', 'infertility AND depression',*

'psychological interventions of infertility', 'cognitive behavioural therapy', and, *'infertility AND domestic violence'.*

The literature was searched from year 2000 onwards. Abstracts of the search findings were read to identify relevant literature which were included in the Endnote reference manager. Although the literature was searched from year 2000, relevant sources of evidence prior to 2000 that would add value to this literature review were also included. References of the identified scientific articles were also searched to source other relevant literature. Scientific databases also recommend relevant literature based on search history, this was also used to further refine the search.

Definitions of infertility

There are debates about using the term 'infertility' in couples with the "inability" to conceive, mainly because this "inability" is often not absolute and is dependent upon various other factors and outcomes. Hence in many texts, the terms "sub fertility", "sub-fecundity" and "infertility" are used interchangeably by different authors (Gurunath et al, 2011).

For a woman, infertility (or a state of subfertility) can manifest itself as either:

1. The inability to become pregnant
2. An inability to maintain a pregnancy
3. An inability to carry a pregnancy to a live birth

However, for both men and women, there are various definitions of infertility. According to WHO (2010) there are clinical, demographic, and epidemiological definitions. Infertility may also be classified as a disability; that is "an impairment of function". This means that access to health care for infertile couples, falls under the Convention on the Rights of Persons with Disability (WHO 2010, 2011; United Nations, 2006).

Historical Definitions of Infertility and the Burden of Disease

Historically, the definition of infertility has evolved over time both in meaning and terminologies used. Over the years, the dynamics of infertility definitions has impacted on the burden of disease by initially putting the focus on one gender (usually women), then to including men in the definition of infertility; to finally achieving the maturity of the neutral and asexual definitions of infertility currently recommend by WHO and other institutions.

Four decades ago, according to a report of a WHO Scientific Group in 1975, the definition of infertility was focused mainly on women. The World Health Organization (1975) defined primary infertility as when a "woman has never conceived despite cohabitation and exposure to pregnancy" over a period of at least two years. It went further to describe secondary infertility as when the *"woman has previously conceived but is subsequently unable to conceive despite cohabitation and exposure to pregnancy for a period of two years…"* Expanding this definition further, the effect of lactational amenorrhoea was considered for the period of infertility in clinical diagnosis (Mascarenhas et al, 2012). Despite this, the burden of infertility was placed solely on women by failing to acknowledge the role of men in the conception process. The 1975 approach to defining infertility promotes infertility-related stigma upon women who have been unable to conceive irrespective of the cause of infertility.

A decade later, the dictionary of demography described infertility as the inability to produce a live birth (Pressat & Wilson, 1985). Although this definition focuses on the outcome of producing a live birth, the focus and the liability was nevertheless laid upon the woman who would 'normally' be expected to give birth to a healthy child alive. The physical evidence, hence the responsibility of conception and childbirth notwithstanding rests upon the woman. Mascarenhas et al (2012) argued however that although the definition term referred to women; men and couples *could* be the focus of attention. Even so, within the same year, the World Health Organisation (1985) produced a manual for investigation and diagnosis of the infertile couple. Like the

previous decade, it accounted for the effect of lactational amenorrhoea but still placed the focus on women by defining infertility as the '*inability of a woman*' to conceive despite cohabitation and the desire to become pregnant for at least 12 months (Rowe et al, 1993).

In 2001, the WHO released infertility indicators in the Reproductive Health Indicators for Global Monitoring (WHO, 2001). Within this context, infertility prevalence is defined as the percentage of women of reproductive age of 15–49 years at risk of pregnancy who are sexually active, not using contraceptives and not breastfeeding but unable to get pregnant for a period of at least 2 years (WHO, 2001). This definition by the WHO in 2001, indirectly reinforced the ideology that infertility was a gender-specific problem. Men with reproductive morbidities leading to infertility were excluded from the defining indicators used to determine the global prevalence of infertility.

In 2004, the National Collaborating Centre for Women's and Children's Health recommended a less gender-specific definition of infertility. They recommended that infertility should be defined as *"…the failure to conceive after regular unprotected sexual intercourse after two years in the absence of a known reproductive pathology"* (NICE, 2004). On one hand, this gender specificity in the NICE definition is less pronounced when compared to infertility definitions in previous years by the WHO. On the other hand, in the NICE definition of infertility; by excluding the absence of a known reproductive pathology, implied that only infertility of unknown aetiology can be classed as infertility. In addition, the term 'failure' within the definition of infertility is stigmatising to those affected, which could impact their identity, further contributing to their psychological distress. Nevertheless, the definition of infertility by NICE has since progressed. According to the National Collaborating Centre for Women's and Children's Health (2013), infertility is defined as "the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented…" (NICE, 2013).

Similarly, the American Society for Reproductive Medicine (2008) defined infertility as a disease characterised by the inability to achieve a

successful pregnancy after 12 months or more of regular unprotected intercourse. It went further to reduce the period of diagnosis, evaluation and treatment to 6 months, for women who are 35 years of age and above; accounting for the effect of age being inversely proportional to infertility in women. More recently, the American Society for Reproductive Medicine described infertility as a condition, occurring as a result of the "disease (an interruption, cessation, or disorder of body functions, systems, or organs of the male and female reproductive tract), which prevents conception of a child or the ability to carry a pregnancy to birth…" (American Society for Reproductive Medicine, 2014). The American Society for Reproductive Medicine's definition distributes the burden equally amongst males and females alike. It also recognises infertility as a circumstance occurring as a result of disorders within the body. This creates an opening to see infertility not only as a medical condition but also within the psychological, social and economic context.

Table 2.1: Definitions of Infertility over time (Mascarenhas et al, 2012)

World Health Organization: The Epidemiology of Infertility – Report of a WHO Scientific Group (1975) Primary infertility: The woman has never conceived despite cohabitation and exposure to pregnancy for at least two years. Secondary infertility: The woman has previously conceived but is subsequently unable to conceive despite cohabitation and exposure to pregnancy for a period of two years; if the woman has breastfed a previous infant, then exposure to pregnancy should be calculated from the end of the period of lactational amenorrhea.
Demographic definition: The dictionary of demography (1985) The inability to produce a live birth. The term usually refers to women, but men or couples can be the focus of attention. Used without qualification, sterility implies irreversibility, but the term temporary sterility is sometimes used.
World Health Organization: Manual for the investigation and diagnosis of the infertile couple (1985) Infertility, primary: The woman has never conceived despite cohabitation, exposure to pregnancy, and the wish to become pregnant for at least 12 months. Infertility, secondary: The woman has previously conceived but is subsequently unable to conceive despite cohabitation, exposure to pregnancy, and the wish to become pregnant for at least 12 months. If the woman has breastfed a previous infant, then exposure to pregnancy should be calculated from the onset of regular menstruation following delivery

World Health Organization: Reproductive Health Indicators for Global Monitoring (2001) Percentage of women of reproductive age (15–49) at risk of pregnancy (not pregnant, sexually active, non-contracepting, and non-lactating) who report trying for a pregnancy for two years or more.
National Institute for Health and Clinical Excellence guideline (2004) Infertility should be defined as the failure to conceive after regular unprotected sexual intercourse after two years in the absence of a known reproductive pathology.
American Society for Reproductive Medicine: Definitions of infertility and recurrent pregnancy loss (2008) Infertility is a disease, defined by the failure to achieve a successful pregnancy after 12 months or more of regular unprotected intercourse. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after six months for women over age 35 years. A distinction is made between primary sterility where a woman has never been able to have a child, and secondary sterility, which occurs after the birth of at least one offspring.
International Committee for Monitoring Technology and World Health Organization: Revised Glossary on ART Terminology (2009) Infertility (clinical definition) is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 or more months of regular unprotected sexual intercourse.

The definitions and terminologies used in describing infertility have been altered and improved over decades. According to the WHO, infertility currently has clinical, demographic and epidemiological definitions which serves different purposes within clinical settings as well as for population studies (Zegers-Hochschild et al, 2009; Rustein & Shah, 2004; Mascarenhas[b] et al, 2012; WHO 2011). These will be described below.

Clinical Definition of Infertility

The International Committee Monitoring Assisted Reproductive Technology (ICMART) and WHO provide a clinical definition of infertility in their revised glossary on ART Terminology. Clinical infertility is defined as a disease of the reproductive system where there is an inability to achieve clinical pregnancy after 12 or more months of regular unprotected sexual intercourse (Zegers-Hochschild et al, 2009). Another definition expresses infertility as the inability of a sexually active couple to achieve pregnancy in

one year without the use of any contraceptive method; whereby the male partner has been evaluated for infertility and sub-fertility using clinical interventions and laboratory evaluation of semen (WHO, 2010). The clinical definition of infertility was developed retrospectively through data collection from individual patients and outcomes measurements during early pregnancy at clinical visits and designed for early detection and treatment of infertility (WHO, 2006; Mascarenhas et al[b], 2012). However, global trends show that induced abortion are largely underreported and household surveys do not include clinical examinations, therefore the documented pregnancy rates are unreliable (Sedgh et al, 2012). While the clinical definition of infertility focuses on both the male and female factors of infertility as equal contributors, it also has the potential to ignore the outcome of a heathy live baby. Late pregnancy complications of still births and neonatal deaths and/ or disabilities are not accounted for. For infertility patients a healthy child is the ultimate outcome wished for, if not, the struggle continues and much remains at stake for the affected couple.

Demographic Definitions of infertility

The demographic infertility definition seems to place its focus on the female partner's ability to produce a live birth rather than as a couple's inability to achieve conception, shifting the outcome to live births, not only conception (Pressat & Wilson, 1985). Here, infertility is defined as the "inability of those of reproductive age (15-49) to become or remain pregnant within five years of exposure to pregnancy" (Rustein & Shah, 2004; Larsen 2000). Mascarenhas[b] et al (2012) also defined infertility as the inability to become pregnant with a live birth, within five years of exposure based upon a consistent sexual intercourse, lack of contraceptive use, non-lactating and maintaining a desire for a child. According to Mascarenhas[b] (2012), the demographic definition of infertility measures infertility at the population level through data collected using household surveys, and is more reliable and accurate, compared with measuring early pregnancy detection.

Unlike the clinical definition of infertility, the demographic definition describes the trends, burden and distribution of infertility within a population on a larger scale. Demographically, it is understandable that a more reliable

outcome should be chosen as a measure of infertility prevalence. Sociocultural, the measurement of live birth as the only indicator for infertility outcomes places the burden of disease on the woman, not the couples involved. The male partner is no longer held accountable for any part in the infertility context. Consequently, this could potentially increase infertility-related stigma and distress for who the woman who already are at a higher risk of marginalization by the community.

Epidemiological Definition of infertility

This definition is used for monitoring and surveillance with its emphasis on involuntary infertility in women. Epidemiologically, infertility is defined as the inability of women of reproductive age (15–49 years) at risk of becoming pregnant – without pregnancy, contraceptive use and lactation, who are sexually active, and have reported trying unsuccessfully for a pregnancy for two years or more (WHO, 1997; 2006; Larsen, 2005). The level of infertility obtained using the epidemiological definition lead to higher estimates and has been criticised as being misleading and unspecific mainly because many couples go on to conceive spontaneously after the stipulated time limit (Larsen & Menken, 1989; Larsen, 2000; Habbema et al, 2004). Moreover, it is difficult collect complete data on number of conceptions in population studies (Sedgh et al, 2012).

For epidemiological studies, it is important to decide on a bench mark for measuring outcomes, in this case of infertility studies, the bench mark is 2 years in agreement with the WHO definition of infertility (WHO, 1978). In reality however, decisions on management of infertility and the likelihood of conception amongst couples varies widely. These dependent on age of couples, duration of actively seeking to conceive, cause of infertility, history of previous conception, and pre-existing co morbidities (Templeton, 2000; Habbema et al, 2004; Kidd et al, 2014). For example, the clinical response to a 38-year-old woman (irrespective of medical history), who has been actively seeking to conceive in the last 12 months would be more urgent than for a healthy 24-year-old woman within the same of period of time. Therefore, irrespective of definitions and terms of reference, management of infertility ought to be patient-centred. These has been in more detail in chapter 4.

Infertility as a Disability

Infertility can be regarded as an impairment of function (a disability), and is ranked the 5th highest disability worldwide amongst women under the age of 60 years (Krahn, 2011). It is estimated that up to 186 million women from '*developing countries*' have infertility, commonly resulting from maternal sepsis and unsafe abortion (WHO, 2013; Krahn 2011). According to the Convention on the Rights of Persons with Disability (2006), the purpose of the legislation is directed towards persons with disability with includes physical and other forms, where by "*interaction with various barriers may hinder their full and effective participation in society on an equal basis with others"*. Here, discrimination on basis of disability is defined as *"….any distinction, exclusion or restriction on the basis of disability which has the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise, on an equal basis with others, of all human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field. It includes all forms of discrimination, including denial of reasonable accommodation…"* (United Nations, 2006; MacKay, 2006).

Based on the definitions and purpose of the legislation above it can be seen that infertility can be classified as a disability within the African context. Nevertheless, this definition is prone to criticism due to its subjectivity. It is largely dependent of the experiences and perception of the people involved, as well as their ability to cope and/or resist adversity. It also depends on the culture within the local context and the value (or lack of it), placed on childbirth, as well as the peculiar (often extreme) consequences attached to infertility, within the particular society in question.

The epidemiology of infertility

Infertility affects 10 – 15% in the Europe and North America, regardless of gender, and up to 30% prevalence in sub-Sahara Africa (Evers, 2002; Mascarenhas et al[a], 2012). It has been estimated that up to one in seven couples will require an infertility specialist for primary or secondary infertility at some point in their lifetime (Hull et al, 1985; Templeton 2000). Male and female partners independently contribute to their fertility as a couple but the

outcomes of fertility are measured only in the female partner as pregnancy rate or incidence of births (Turchi, 2015). It has been suggested that there are limitations in the epidemiologic studies of infertility mainly because the male factor contributions to infertility are underestimated due to the difficulty in evaluating which partner contributes the most to a couple's inability to conceive; especially when male and female factors are both responsible for a couple's infertility. (Turchi, 2015; Pescatori, 2015).

Male infertility is a major cause of infertility in couples, accounting for about 26% of cases but this condition is visibly expressed through the woman as her inability to become pregnant (Evers, 2002). Regardless of the clinical cause of infertility, women carry the larger burden in many African societies in forms of social stigma, personal grief and even deprivation in other cases (Whitehouse & Hollos, 2014). Infertility success outcomes are measured mainly as the incidence of pregnancy in females while the time to pregnancy (TTP) in males are confined only to diagnostic guidelines for semen analysis in males (Turchi, 2015). Hence, when there is no pregnancy, the perceived root cause is laid initially at the woman door and the general assumption in the community is that a disease or disability is preventing her from getting pregnant (Inhorn & van Balen, 2002). Irrespective of its clinical and social burden in African societies, infertility receives very little attention in terms of the development of health initiatives and programmes due to limitations in resources as well as fast growing populations in Africa being valued as a larger problem (Dhont et al, 2011).

Generally, it is believed that over 90% of couples will have conceived after regular unprotected sexual intercourse for 3 years (Kamath & Bhattacharya, 2012). The Demographic and Health surveys program estimate that 167 million women (aged 15-49 years), who have ever been married in developing countries were infertile in 2002; these rates exceed 30% in sub-Sahara Africa (Rutstein & Shah, 2004). The high level of infertility in Africa is mainly attributed to reproductive tract infections. These not only cause abnormal semen parameters and low sperm count in men, but also tubal blockage in women (Abrikwu et al, 2013). Many researchers have demonstrated the very high prevalence of infertility in Africa, most especially

in the sub-Sahara region, as it accounts for more than half of patients seen in gynaecological clinic within this region (Araoye, 2003; Larsen, 2000; Gerias & Rushwan, 1992). The high prevalence is associated also with the high frequency of sexually transmitted infections (STI), pelvic inflammatory diseases (PID) and the unsafe abortion practices within the region (Araoye, 2003; Gerias & Rushwan, 1992). The majority of African communities that experience high levels of infertility also experience co-existing high fertility rates (Cates et al, 1985; Templeton 2000; Mascarenhas et al, 2012). Both after all, are outcomes of sexual intercourse in settings with few gynaecological services and uptake, for contraception or STI management. Some researchers even consider that the high fertility rates are driven in part by the persistently high rates of infertility and its consequences, which creates a reluctance among women to initiate contraception for fear of putting their subsequent fertility at risk (Cates et al, 1985).

Overall, there are several factors that are known to hinder natural conception and these include: Age- where fertility declines rapidly in women after the age of 35 years, lifestyle choices such as smoking, excessive alcohol and coital frequency, as well as certain occupational hazards like exposure to certain chemicals and radiation. Furthermore, being overweight or underweight affects ovulation hence making conception much harder. Some drugs are known to reduce couples' chances of conception and these include chemotherapy treatments which destroy rapidly dividing cells as seen in gametes, and drugs that affect sperm cell quality or morphology such as cimetidine, sulphasalazine and androgen injections (Collier, 2003).

The World Health Organisation (1992) estimated that 8 to 12% of couples worldwide experience difficulty conceiving a child. Generally, it is expected that 60% of women will conceive after 6 months and 84% within 1 year of regular unprotected sexual intercourse, 92% after 2 years, and 93% after 3 years (Kamath & Bhattacharya, 2012). Approximately one-third of cases of couples' infertility are known to be caused by male factors, one-third to female factors and one-third relates to a combination of male and female factors or has no identifiable cause (Johnson and Everitt, 2000). However, the real estimate of infertility is difficult to assess and estimated prevalence of

infertility globally varies widely as a result of variations in definitions of infertility by clinicians, epidemiologists and demographers as well as differences in expected outcomes and criteria such as a history of previous conception, clinical pregnancy or the attainment of a live birth (Gurunath et al, 2011).

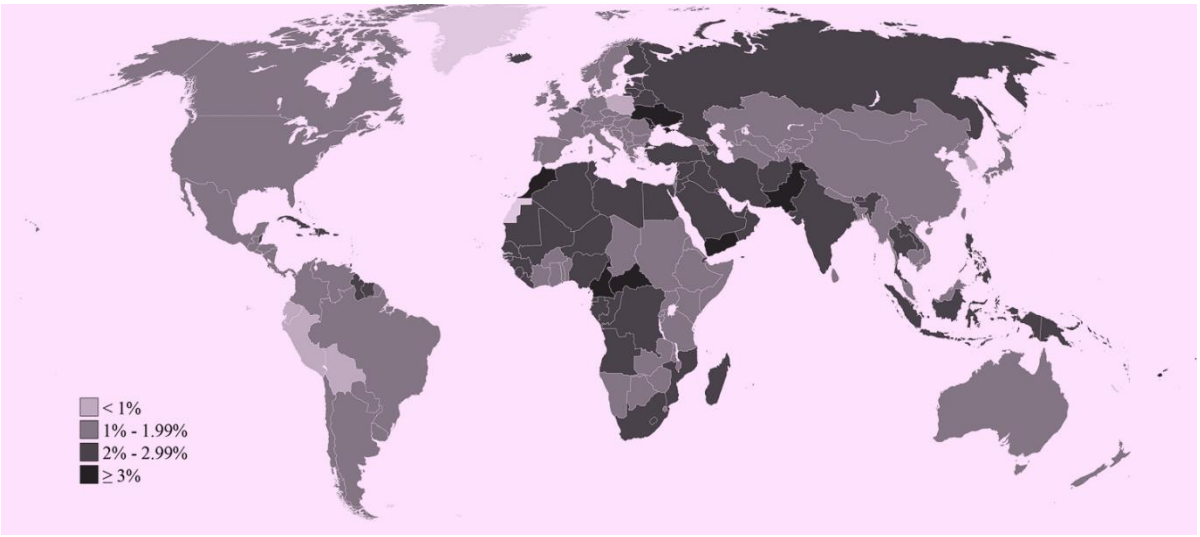


Fig 2.1: Global infertility prevalence since 1990 from a systematic analysis of 277 health surveys, extracted from Mascarenhas et al (2012). *[This figure was sourced from an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.]*

Epidemiology of Infertility in Nigeria:

Nigeria remains the most populated country in Africa and here, infertility problems account for 60-70% of all gynaecological consultations in tertiary health institutions, hence pronounced *"the most important reproductive health concern of women in Nigeria"* (Okonofua, 2003; Megafu, 1988). In 2012, Nigeria recorded a total population of 169 million people with an average life expectancy of 52 years in women and 54 years in men (WHO, 2012). The Nigerian population has since increased to approximately 197

million, which accounts for almost 47% of West Africa's population, and one of the largest youth population in the world (World bank, 2019). Although there has also been also been a slight increase in average life expectancy recorded in 2016 as 55 years and 56 years in males and females respectively, it remains dismal when compared with other developed countries in the world (WHO, 2016). The normal reproductive age group is generally described between the ages of 19-49 years in women. It is possible that the short life expectancy puts added pressure on people living within this region to reproduce in "good time". When pregnancy is delayed it pressurises couples to consider multiple measures often leading to desperation and ill-advised choices. Infertility rates in Nigeria are recorded to be as high as 20% of the population, and the male factor contributes to almost half of the cases (Abarikwu, 2013; Larsen, 2000; Okonofua et al, 1997). This means that an estimated 39. 4 million people in Nigeria are dealing with infertility. Giving the physical, financial, psychological and sociocultural implications of infertility in the Nigerian context, infertility therefore is a major health issue, and should be treated as such.

Amongst infertility patients in southeast Nigeria, 65% of all infertility cases are primary while 35% are as a result of secondary infertility- male only causes accounted for 42.4%, female only 25.8%, both partners 20.7%, and unexplained causes in 11.1% of infertility patients (Ikechebelu et al, 2003). In southwest Nigeria, the incidence of infertility was found to be 14.8% of gynaecology outpatient cases with the male factor accounting for a little less at 26.8%, female factor higher at 51.8% and a combination of male and female factors were recorded in 21.4% cases and the incidence of infertility was found to be 14.8% (Olatunji & Sule-Odu, 2003). In Northern Nigeria, a study by Panti et al (2014) recorded the prevalence of infertility in 15.7% of patients with a higher proportion of secondary infertility (67.2%), compared to primary infertility (32.8%). Female factor infertility accounted for 42.9% of infertility patients, male factor was found in 19.7%, combined male and female factor contributed to 16.7%, while unknown causes was recorded in 20.7% of infertility cases (Panti & Sununu, 2014).

According to Araoye (2003), the predominant cause of primary infertility in Nigeria is as a result of the male factor, it also accounts for almost half of all infertility cases in Nigeria. The global decline in the semen quality of young healthy men has also been reported in Nigeria; this has been associated with exposure to heavy metals such as cadmium and lead, mycotoxins such as aflatoxins, pesticides, industrial chemicals, as well as other endocrine factors (Abarikwu, 2013; Akinloye et al, 2005, Ibeh et al, 1994). According to Ibeh, higher concentrations of aflatoxin B1 (AFB1) were found in the semen of infertile Nigerian men than in fertile controls which suggests that the consumption of AFB1 contaminated diets may predispose to male infertility. Previous exposure to spermatotoxic and steroidal drugs such as cimetidine, sulfasalazine, nitrofurantoin, and cannabis, as well as surgical procedures, such as hernia repairs and the use of native medications also contribute to the prevalence of male infertility amongst Nigerian men (Akinloye et al, 2005).

In addition to environmental factors, the high prevalence of sexually transmitted infections and genito-urinary tract infections also contribute significantly to male and female infertility in Nigeria. In many countries below the Sahara- Nigeria inclusive, inadequate or non-treatments of sexually transmitted diseases are responsible for 50-80% of infertility cases (Ahmed et al, 2010). A study done amongst male partners of infertile couples in Ile -Ife, Nigeria, showed that 57.6% had normal seminal fluid analysis, 27.7% were oligozoospermic and 15.2% had azoospermia, with 62% of the couples with secondary infertility having a significant past history of sexually transmitted diseases (Esimai et al, 2002). In northern Nigeria, a study showed that 9.6% of infertility patients tested positive for *Chlamydia trachomatis*, majority of whom were not aware of having the infection and unfamiliar with its complications (Nwankwo & Magaji, 2014). Panti et al (2014), also showed that it was commonly reported amongst infertility patients in Northern Nigeria, a prevalent previous history of genital infection, self-reported as lower abdominal pain (78.8%) and vaginal discharge (76.6%), with patients being oblivious to cause of the symptoms.

Studies in Nigeria have demonstrated infertility as major health problem with strong links between STIs and infertility. It also shows

occupational and environmental hazards that predispose men and women to infertility, irrespective of socio-economic class. The common causes of infertility in Nigeria are preventable, if appropriate health policies are in place to tackle the health issues, thereby reducing the avoidable high incidence of infertility and its burdens. While some patients may be able to afford infertility treatment, majority do not have the financial means, therefore are at risk of falling into the hands of unqualified 'specialist'. Additionally, there are established strong association between STIs and HIV infection. People who are actively seeking conception are very unlikely to practise safe sex as well as to indulge in multiple sexual partners, further increasing the risk of the spread of HIV and other STIs (Favot et al, 1997). For infertility patients, the main focus is conception; every other issue is secondary and relatively unimportant. Nonetheless, addressing infertility is more than being about conception and/or population control, it is also a sexual and reproductive health issue that has the potential to put the larger population at risk of spread of STI, further adding to mortality and morbidity rates.

Infertility Types and Causes

Types of Female Infertility

Primary infertility

Women who have never been pregnant and who are unable to conceive a child after a year of unprotected sexual intercourse are classified under primary infertility. Clinically, primary infertility encapsulates the inability of a woman to ever produce a live birth, either as a result of an inability to become pregnant or the inability to carry a pregnancy to a live birth which includes previous miscarriages or still births. (Mascarenhas[a] et al, 2012). The prevalence of primary infertility is relatively low in sub-Sahara Africa, accounting for only 2-3% on the average. It exceeds 3% in less than a third of 28 African countries with the highest prevalence reaching 6% in Cameroon and Central African Republic (Larsen, 2000; Araoye, 2003; Mascarenhas[a] et al, 2012). In Nigeria, the prevalence of primary infertility derived from the 1993 Demographic Health Survey was 4% of the population (Larsen, 2000).

Primary infertility also accounts for up to 35% of infertility cases in Nigeria (Ikechebelu et al, 2003; Olatunji & Sule-Odu, 2003; Panti & Sununu, 2014).

Secondary infertility

Secondary infertility is defined as the inability to become pregnant, or to carry a pregnancy to term, following a previous pregnancy and/or the birth of one or more biological children whereby the birth of the first child does not involve any assisted reproductive technologies or fertility medications. When a woman is unable to bear a child, either due to the inability to become pregnant or the inability to carry a pregnancy to a live birth following either a previous pregnancy or a previous ability to carry a pregnancy to a live birth, she would be classified as having secondary infertility. Thus, those who repeatedly spontaneously miscarry or whose pregnancy results in a stillbirth resulting in the inability to carry a pregnancy until the delivery of a live birth would present with secondary infertility. (Mascarenhas[a] et al, 2012). Secondary infertility carries a larger burden in sub-Sahara Africa and spreads widely across the region. The highest prevalence of secondary infertility is seen in Central African Republic (Congo) with 25%, followed by Cameroon which represents 20% of the population (Larsen, 2000; Araoye, 2003; Mascarenhas[b] et al, 2012). In Nigeria, the prevalence of secondary infertility is 15-19% of the population, in comparison to primary infertility which is considerably less in prevalence at only 4%.

The reason behind this could be attributed to the high incidence of termination of unwanted pregnancies and unsafe abortion practices that contribute largely to Pelvic Inflammatory Diseases (PID) (Etuk, 2009). PID and Sexually Transmitted Infections (STI) together constitute the commonest aetiology of infertility in Nigeria and the infertility belt of sub-Sahara Africa. STIs are also caused by unprotected sexual practices which could lead to unwanted pregnancies. Induced abortion is illegal in Nigeria with up 14-year jail sentence penalty (Ibekwe, 2007). Sixty percent of abortions done in Nigeria are unsafe and in unhygienic conditions, causing infection, PID and 20% of maternal mortality (Henshaw et al, 1998; Adefuye et al, 2003; Etuk, 2009). Asherman's syndrome, which is the development of scar tissue on the endometrial lining as a result of excessive curettage during surgical abortions

also contributes to infertility especially within African populations (Etuk, 2009)

The linked associations between unwanted pregnancies, unsafe abortions, PID and STIs is a major issue amongst among adolescents and young adults who are not ready for the responsibility of parenthood. When access to right information is limited, the become potential victims of unqualified and unskilled health personnel carrying out abortions illegally, leading to trauma, infections, and reproductive problems in later life.

Causes of Female Infertility

The main 3 causes of female infertility are a dysfunction in the hypothalamic-pituitary-ovarian (HPO) axis and ovarian factors (both of which cause problems with normal ovulation), tubal factors (caused by blockage of the fallopian tubes), and endometrial factors (mainly endometriosis and uterine fibroids). Unknown causes of infertility accounts for up to 25% of female infertility (Ikechebelu et al, 2003; Roupa et al, 2009; Panti & Sununu, 2014).

Ovarian factors

The HPO axis is important for normal ovarian function because it regulates the release of specific hormones such as the gonadotrophin-releasing hormone (GnRH) which acts on the pituitary gland in the brain to regulate normal release of the Follicle Stimulating Hormone (FSH) responsible for normal development of oocytes (eggs), and the Luteinizing Hormone (LH) that stimulates the release of the eggs hence ovulation. Anything that causes imbalances within the HPO axis will invariably affect normal ovulation hence fertility is compromised. Identified factors that may precipitate this effect include stress and other psychological disturbances, rapid or abnormal weight gain or loss (BMI <19 or >29).

Excessive weight loss and weight gain cause ovarian dysfunction leading to infertility. Obesity has quickly become a major health issue in Nigeria. The prevalence of overweight and obesity in Nigeria are up to 35.1% and 22.2% of the population, respectively (Adedoyin et al, 2009; Amira et al,

2011; Oyeyemi et al, 2012). Studies have linked obesity with polycystic ovarian syndrome, a common cause of infertility through the development of hyperandrogenism in women with PCOS. Globally, the commonest cause of infertility associated with anovulatory infertility is polycystic ovarian syndrome (Seli & Duleba, 2002). A study in Enugu, Nigeria showed PCOS accounted for 18.1% of women; it manifests as infertility in 83% of the women, oligomenorrhoea in 73%, obesity in 52%, abnormal LH/FSH ratio 45%, hyperprolactinaemia in 42%, and hirsutism in 30 % of the women (Ugwu et al, 2013).

Other ovarian factors are premature ovarian insufficiency occurs when there is total failure of the ovaries in women under the age of 40 years. There are also iatrogenic causes such as pelvic surgery, irradiation and cytotoxic drug treatments. Finally, there are known viral infections and autoimmune disorders which may result in ovarian failure.

Tubal Factors

Tubal factors causing infertility are more commonly seen in women presenting with secondary infertility and in populations with a higher prevalence of sexually transmitted disease leading to pelvic infection and pelvic inflammatory disease. Infections, pelvic surgery and inflammatory processes within the abdominal and pelvic cavity may result in formation of scars and adhesions. When the fallopian tubes become affected it results in blockage in the proximal, mid or distal parts of the fallopian tubes.

Untreated chronic pelvic infection is a common cause of infertility in sub-Sahara Africa which has been shown in the "infertility belt" (Mascarenhas[a,b] et al, 2012). The regions described within the African continent affected by the highest global prevalence of infertility which stretches from east through central Africa to west Africa, with the highest prevalence see in Cameroon, Central African Republic (Congo), and Uganda (Agarwal et al, 2015; Mascarenhas et al, 2012). The burden STI related infertility in Nigeria have been discussed in details in the '*epidemiology of infertility'* section of this chapter.

Tubal patency is commonly tested the hysterosalpingogram (HSG) as a first choice as it is less invasive than laparoscopy (Gelbaya et al, 2014). HSG is also less costly as it does not require general anaesthesia. However, it is less accurate in determining the extent of tubal damage and function (Tanahatoe et al, 2008; Opsahl et al, 1993). It is possible that tubal function can be abnormal in the presence of "normal" tubal patency on HSG (Karande et al, 1995; Papaioannou et al, 2003). According to Karande et al, (1995), tubal abnormalities which can be anatomical or physiological can stay invisible in 85% of infertility cases. Although laparoscopy comes at a greater cost financially and physically, studies show it is able to detect abnormalities in up to 68% of patients with previously normal HSG results (Henig et al, 1991; Corson et al, 2000). Many factors such as late recognition, poor treatment and/or compliance with treatments, difficulty in access to care, and reoccurrence of infection, contribute to the high prevalence of tubal damage after PID. This makes HSG a less safe as a diagnostic method due its disadvantages which include pain and discomfort, infection, risk of dye embolism, exposure to radiation and iodine hypersensitivity (Anwar & Anwar, 2016).

Unfortunately, many patients in resource limited settings of Nigeria may not have access sophisticated diagnostic procedures such as laparoscopy which are more accurate, due to its the high cost. This means that they rely on HSG for diagnosis, with less optimal accuracy, which could lead to wrong diagnosis, inappropriate treatment of infertility and undue extension of infertility duration. Additionally, a higher incidence of tubal abnormalities has been reported amongst patients undergoing assisted reproductive techniques (ART) who suffer from endometriosis (Guzick et al, 1994; Fakih et al, 1994; Papaioannou et al, 2003). Endometriosis is diagnosed by laparoscopy. Gleicher et al (2006) reasons that in some women who have been diagnosed with unexplained infertility with patent tubes, there may be an *"undiagnosed underlying tubal damage resulting from endometriosis"*.

Endometrial factors including uterine fibroids

Successful implantation of an embryo and the normal progression of pregnancy is dependent upon having a normal healthy endometrium. The

presence of adhesions, uterine fibroids and uterine polyps result in abnormalities in the lining of the womb (the endometrial and the normal structure of the endometrial cavity thus preventing normal healthy implantation of an embryo or causing miscarriage of an implanted embryo). There is a known higher prevalence of uterine fibroids in women of African origin with its peak incidence occurring in women in between the ages of 30-40 years, and is it is estimated that 20% - 45% of women above the age of 30 years have uterine fibroids (Akinyemi et al, 2004; Ezeama et al, 2012). Uterine fibroids (especially sub-mucous type) may distort the endometrial cavity, preventing implantation.

In Nigeria, uterine fibroids are a very common condition that has been linked with infertility. A study by Aboyegi et al (2003), found that uterine fibroids amounted to 13.4% of gynaecological admission, accounting for 26.2% of major gynaecological surgery (Aboyegi & Ijaiya, 2003). It is thought that the growth of the fibroids is as a result of a *'hyperestrogenic environment'* which could cause anovulatory cycles (Buttram et al, 1981). Also, the pathological changes in uterine shape and size can cause distortion, abnormal sperm migration and ovum transport (Richards et al, 1998). A study by Casini et al (2006) corroborates the role of uterine fibroid in the prevalence of infertility, as outcomes showed achievement of a viable pregnancy after successful uterine fibroid removal surgery (Casini et al, 2006).

Male Infertility

Studies indicate that 30-50% of infertility is related to male factors such as structural abnormalities, sperm production disorders, ejaculatory disturbances and immunologic disorders (Abarikwu, 2013; Templeton, 2000; Everitt, 2000). According to Everitt et al (2000) a third of cases of couples' infertility is caused by male factors, the second third is due to female factors and the last third is as a result of a combination both male and female factors or without any identifiable cause (Johnson and Everitt, 2000).

Spermatogenesis, the production of sperm cells (spermatozoa) begins at puberty and continues throughout life. The process takes about 74 days, plus another 10 days for sperm cells to travel and be stored in the epididymis, ready

for ejaculation. The entire process of spermatozoa production is regulated by LH, FSH and testosterone hormones. LH produced from the pituitary gland stimulates the Leydig cells in the testis to produce testosterone. Testosterone and FSH stimulate Sertoli cells, which are highly specialised cells in the seminiferous tubule lining, responsible for optimal development, nourishment and metabolism of sperm cells (Monga & Dobbs, 2011). Anything that affects this smooth operation of this delicate system, impacts quality of sperm cells, thereby contributing to infertility in males.

Causes of Male Infertility

According to Smit et al (2010), about 8% males within reproductive age groups come to seek medical assistance for infertility problems. Generally, any factor which affects normal sperm cell production, transportation of semen and the ejaculation of semen at the right time can affect male fertility. These factors can be genetic, anatomical, physiological, pathological, mechanical or environmental. Ninety percent of male infertility cases are as a result of low sperm count and/or poor sperm quality (Leaver, 2016). Even though male infertility is a major cause of infertility in couples, accounting for about 30% of cases; it can only be expressed through the woman (Evers, 2002; Faraj et al, 2016). STI-related infertility accounts for the majority of infertility seen in Nigeria; these have been discussed in details in the '*epidemiology of infertility*' section of this chapter. Infection of the seminal fluid also cause of azoospermia by causing damage to the vas deferens and seminiferous tubules, affecting FSH, LH, and testosterone hormonal levels (Megafu, 1991).

Hypothalamic or pituitary dysfunction leading to impaired sperm function, accounts also for male factor infertility (Comhare 1978; Faraj, 2016). Hypogonadism lead to testicular failure and affects spermatogenesis by causing a decline in the level of testosterone produced by the body (Jungwirth et al, 2015; Hull et al, 1985) Male infertility can be caused by congenital abnormalities presenting in adulthood; these conditions are however less common in Nigeria when compared with other causes of infertility. Unusual conditions such as posterior urethral valve, a congenital malformation characterised by development of membranes in the posterior urethra, leading

to obstruction (Agbugui & Omokhudu, 2014; Juul et al, 2014). Hypospadias is another congenital abnormality that can mechanically impair reproductive techniques and conception by the inability of the male partner to deposit semen high up in the vagina (depending on where urethral opening is located), during sexual intercourse (Juul et al, 2014; Leaver, 2016).

Other significant causes of male infertility results from trauma, torsion and diseases such as orchitis and systemic inflammatory diseases (Su et al, 2014; Ahmadi et al, 2016). The causes of male infertility are summarised in Table 2.2.

Table 2.2: Causes of male infertility

Seminal fluid and sperm abnormalities	a) Low sperm count (Oligospermia) or a complete absence of sperm cells (Azoospermia). b) Decreased sperm mobility. c) Abnormal sperm morphology.
Testicular causes	d) Testicular infection resulting from mumps, STIs. e) Testicular cancer. f) Iatrogenic causes (testicular surgery, herniorrhaphy post-vasectomy unsuccessfully reversal). g) Congenital abnormalities such as undescended testis h) Testicular trauma i) Varicocele
Problems with ejaculation	j) Retrograde ejaculation. k) Premature ejaculation.
Hypogonadism	l) Low level of testosterone caused by tumours, drugs such as cannabis, Klinefelters Syndrome.
Drugs and herbal supplements	m) Drugs- sulphasalazine, anabolic steroids, nitrofurantoin chemotherapy. n) Herbal medicines- e.g. Tripterygium wilfordii (affects sperm cell production and reduces testicular size).
Lifestyle	o) Excessive alcohol consumption, tobacco smoking.
Heavy metals	p) exposure to heavy metals such as cadmium and lead.
Toxins	q) mycotoxins such as aflatoxins, pesticides, and industrial chemicals.

Diagnosis of Male Infertility

Clinically, male fertility is measured by seminal fluid analysis (SFA) which investigates the quality and amount of sperm cells produced. The seminal volume, sperm count, sperm cell morphology, and presence of antibodies or infection are examined to see whether they are within normal range for a healthy male. Over the years there have been changes in "normal" sperm cell count and seminal fluid volume at a rate of approximately 1-3% decline a year between 1938 and 1990 (Carlsen et al, 1992; Swan et al, 1997). In 2010, the WHO released the 5th Edition manual of laboratory guidelines for seminal fluid analysis. The sperm count suggested by WHO was lower than the guidelines in the two previous decades (World Health Organisation, 1987, 1992, 1999 and 2010; Cooper et al, 2010; La Vignera et al, 2012). Changes in sperm density over the years have been attributed to environmental factors, and increases in genitourinary abnormalities such as testicular cancer and genitourinary infections (Carlsen et al, 1992; Swan et al, 2000).

The new reference values by WHO (2010) suggest 6% strict morphology, 16 million sperm/mL, and 40% progressive motility as normal sperm analysis. However, the source of the new reference range have been criticised for under-representation of the global population. The report by Cooper et al (2010), the authors of the 2010 WHO guidelines, suggested that reference values were generated from results of studies mainly from Northern Europe, Australia and the United States leading to an overrepresentation of data from those countries. Data from other parts of the world, such as Africa, parts of Eastern Europe, Central America and South America were largely underrepresented, therefore marginalised. Furthermore, the reference limits for the fertile population used to generate the guideline values with known Time to Pregnancy (TTP) came only from Northern Europe, Australia, and the United States. This indicates that the fertility of men living in other parts of the world (including Africa), were not included into the data and analysis used to generate the reference values by which their fertility is concluded and diagnosed.

There are also concerns about the use of seminal fluid analysis (SFA) as the main diagnostic factor of male infertility clinically. According to Filimberti et al (2013), the male fertility status is poorly indicated by semen analysis because it gives information on the male genital system in isolation, indirectly indicating the reproductive abilities of the male reproductive system. Semen analysis does not consider other factors such as factors such as sexuality, frequency of sexual activity and techniques; all of which have their effect on a male's capacity to contribute to conception in a female. Likewise, the seminal examination and analysis is subjective and dependent on the examiner skills and experience, consequently, it has a high coefficient of variability (Filimberti et al, 2013; Turchi, 2014).

Unexplained Infertility

Unexplained infertility is diagnosed when the common causes of infertility are eliminated by standard fertility investigations (Crosignani et al, 1993; Templeton 2000). According to Zegers-Hochschild et al (2009), the prevalence of infertility globally is approximately 14%, affecting approximately 1 in 7 couples. However, it is calculated that a typical fertility evaluation will fail to identify an abnormality in approximately 15% to 30% of couples presenting with infertility (Gelbaya et al, 2014). Unexplained infertility is responsible for nearly 40% of female infertility, and up to 28% of infertility in couples (Hull et al, 1985; Thonneau et al, 1991). Evidence shows the age of a woman is the most significant prognostic factor for naturally successful conceptions and after the age of 30 years, the level of conception lowers considerably (Hull et al, 1985; Polyzos et al, 2008). Next to the age of the woman, the duration of infertility is another important prognostic factor for infertility (Hull et al, 1985; Templeton, 2000; Collins et al, 1995; Snick et al, 1996).

Similarly, in males, studies suggest age above 45 years is associated with decreased sperm quality (Kidd et al, 2001; Hassan & Killick, 2003). The sperm volume, motility and morphology but not the sperm concentration, were significantly reduced in men over the age of 50 years when compared

with those aged 30 years or less (Kidd et al, 2001; Paulson et al, 2001). There was also a fivefold increase in TTP (causing up to 2 years delay) in men aged 45 years or more, when compared with men less than 25 years old (Baird et al, 1986; Hassan & Killick, 2003). Nevertheless, results from Paulson et al (2001) suggests that although there is significant decline in sperm count, the change did not reflect a decreased fertilization rate or live births in the oocyte donation model during assisted reproduction (Paulson et al, 2001). In general, amongst couples with unexplained infertility with 12 months of unsuccessful attempts, about 50% will conceive in the following 1 year and another 12% within the year after (Bongaarts, 1975; Te Velde et al, 2000).

Fertility studies highlight prognostic factors that can be used as a guide for decision making during patient care for fertility treatments (Leushuis et al, 2009; table 2.3). The chances of spontaneous pregnancy can be estimated in couples with unexplained infertility using the Hunault prognostic model (Hunault et al., 2004; van der Steeg et al., 2007). The Hunault prognostic model is a predictive model for spontaneous pregnancy used to determine if treatment is required or expectant management would be beneficial for the patient. It was developed from a cohort of sub fertile women from which determinant factors indicated those who would not be expected to conceive naturally from those with spontaneous pregnancy within a period of time (Hunault et al., 2004; McLernon et al, 2014). If the possibility of normal conception is 30% or more within a 12-month period; this is measured as a good Hunault Prognosis. This means that medically assisted infertility treatment does not increase the probability of an ongoing pregnancy when compared expectantly management of infertility for 6–12 months; also known as Tailored Expectant Management-TEM (Steures et al., 2008; Custers et al., 2012).

The recent European guidelines advise Tailored Expectant Management for 6–12 months to prevent overtreatment (National Institute of Clinical Excellence (NICE) and the Dutch Society for Obstetrics and Gynaecology (NVOG). A study by Kersten et al (2014), determined the prevalence of overtreatment in couples with unexplained infertility. Results showed that 36% of couples who would have been eligible for TEM were

treated too early using medically assisted reproduction (MAR). This leads to unnecessary costs, anxiety and interventions. It could also cause needless waiting times for infertility treatments, generate an unwanted burden on health resources, therefore increasing the strain and stress on the patients and health workers. While it makes economic and clinical sense to adopt the European guidelines, managing infertility socially within African context (including Nigeria) is not as straightforward. When infertility is unexplained, the attention is directed to the woman as the possible cause of infertility, within the community. Therefore the 'wait and see' approach might be misinterpreted as the couple not putting in the 'proper' effort to overcome infertility, leading to impatience and reprimand from the extended family members. These issues need to be carefully considered when opting for TEM, in addition to providing suitable psychosocial support for infertility patients during those waiting times.

Inversely, the high cost of infertility treatments means that not everyone can afford the costs of fertility care, especially in resource poor settings. Thus, it is unfair and unreasonable to spend on needless fertility treatments. It would also be unusual to receive insurance reimbursement even after established unrequired treatments as majority of health insurance policies do not cover for infertility treatments (Chambers et al, 2012; Jones et al, 2011). It becomes essential nevertheless to avoid unnecessary costs in order to lessen the negative impact of infertility on couples (van den Boogaard et al, 2013). It is also more beneficial towards patients to prevent needless exposure to the dangers and difficulties associated with invasive treatments, especially when it cannot guarantee a healthy pregnancy (Verhaak et al, 2002; Helmerhorst et al, 2004; Steures et al, 2008; Verberg et al, 2008; Custers et al, 2012).

Table 2.3: Prognostic factors used to predict spontaneous pregnancy (Leushuis et al, 2009).

Couple factors	Duration of subfertility Secondary subfertility
Female factors	Female age Referral status Ovulation disorder Pelvic surgery Tubal defect Endometriosis Ovulation or cervical disorder Uterine abnormality (UA) UA and ovulation or cervical disorder
Male factors	Male age Sperm motility Degree of motility Sperm morphology Sperm concentration (x 10^6) Abnormal post coital test WHO semen defect Hypo-osmotic test Urethritis in history Fertility problem in male's family

Cost of infertility in Nigeria

The cost of infertility in many African societies reaches way beyond just finance. It has psychological, sociocultural and even religious implications and costs. These have major effects including its consequences on the help seeking behaviour of infertile couples such as choices and attitudes to treatment (Dutney, 2006; Okonofua et al, 1997; Berg et al, 1991). Although male factors contribute to about half of all cases of infertility, African women are often held responsible for couples' inability to conceive. They also bear the majority of the burden of treatments with the accompanying distress and discomforts (Hammarberg & Kirkman, 2013; Berg et al, 1991). Women are also more likely to carry the psychological and sociocultural burdens of infertility. Research shows infertility in a woman increases the possibility that her human rights will be violated and her negotiating power within the family and society is greatly reduced as a result of her "failure" to procreate (Antai & Antai, 2008; Castro et al, 2008). Studies conducted in Nigeria and Ghana revealed that

women's treatment in the community, their self-respect and understanding of womanhood depend on motherhood (Hollos et al, 2009) and that women experience social stigma, relationship problems and diminished emotional wellbeing as a result of being infertile (Fledderjohann, 2012). Women in Ghana also described how the blame for infertility has been disproportionately attributed to women (Fledderjohann, 2012; Donkor & Sandall, 2007).

The ability to procreate is perceived as essential in the vast majority of African societies, irrespective of its matrilineal or patrilineal societal structure. Here, the ultimate purpose of marriage is to produce children who will continue the heritage and name of the family, to guarantee a continuum of the lineage, and as a social security in the old age (Donkor & Sandall, 2007). Thus, motherhood is considered a major role of women and a respected female identity. Even in parts of Africa with matrilineal societies such as Ghana, the attitudes are favoured toward child bearing and there is a societal stigma related to infertility (Fledderjohann, 2012; Donkor & Sandall, 2007).

Many researchers have examined the social and psychological consequences of infertility in African societies. The results show that infertility is a recognised cause of anxiety and depression as well as a major root cause of marital discord and domestic violence amongst African couples (Antai & Antai, 2008; Ardabily et al, 2011). This further worsens the rate of stress-related disorders, increasing depression, anxiety, psychosomatic symptoms, eating disorders, and sexual dysfunction (Ardabily et al, 2011; Antai & Antai, 2008; Castro et al, 2008; Dutton & Nicholls, 2005; Xu et al, 2005). In a study carried out in Iran by Ardabily et al (2011), the prevalence of domestic violence against women with female factor infertility was found to be 61.8%, much higher than the 1.8% reported from Hong Kong and the 33.6% reported from Turkey. Dutton & Nicholls (2005) explains that although domestic violence can occur to both men and women as victims, the effects of it are observed to be more severe in women, with the potential to have detrimental effects on health, including their reproductive health (Dutton & Nicholls, 2005). The statistics of infertility and the multiple complexities associated with dealing with it indicate the vicious cycle of anxiety and worry to those affected on a daily basis, particularly for women in African communities.

In addition to the physical and psychological consequences of infertility, there are financial implications to accessing treatment in low- and middle-income countries (Rouchou, 2013; Cui, 2010). In North America, a study carried out by the Institutional Review Board at the University of California, San Francisco (Wu et al, 2013) prospectively characterized the time couples spent pursuing fertility care. They found an average duration of 125 hours within an 18-month period. The overall physical, financial and emotional costs of treatment was cited as a major reason why patients choose not to pursue fertility care, or why they discontinue care before achieving pregnancy (Wu et al, 2013). In Nigeria, the general government expenditure on health as a percentage is only 5.6% of general government expenditure (worldbank.org). Majority of Nigerians have no health insurance despite the launch of National Health Insurance Scheme (NHIS) in 2006, and therefore forced to rely on out-of-pocket payments for health tipping many families into poverty (Aregbesola, 2016). The out of pocket spending according to the World Bank in 2015 was 72.2%. The "out of pocket expenditure" as defined by the World Bank is

> *"…. any direct outlay by households… whose primary intent is to contribute to the restoration or enhancement of the health status of individuals or population groups… part of private health expenditure…"* (worldbank.org).

Nigeria, despite being an oil rich country has more than half of its population living in poverty. Although Nigeria is ranked as the 3rd biggest economy in Africa, the country is positioned in the bottom 10th percentile on the Human Development Index-HDI scale (UNDP, 2018). Since the health sector reforms in 1980s, which saw the introduction of user fees, the cost of receiving health care has increasingly fallen on the patients and their families. Infertility, unlike many other non-communicable conditions prevalent in sub-Sahara Africa, can affect any person irrespective of socio-economic standing. Moreover, infertility is not categorised as a priority on the health agenda of Nigerian health care policy makers or even on the global health agenda (Fleetwood & Campo-Engelstein, 2010; Akinloye & Truter 2011.). Invariably in Nigeria, the cost of the treatments lies with those couples experiencing infertility. Since the development of IVF and micro insemination techniques,

the chances of conception have markedly increased in infertile couples who would otherwise have been left with no other option but sperm donation or adoption (Brezina & Zhao, 2012). However, these procedures are very costly and not accessible in many parts of the country, further complicating the stress that infertile couples have to endure in order to receive treatment and to conceive a healthy pregnancy.

Adoption, on the other hand, carries a lower financial burden. However, there is a poor attitude towards adoption, due to a lack of understanding of the meaning, process and legal implications. There are often also uncertainties about the adopted child's allegiance by not choosing to return to biological family in future (Oladokun et al, 2009; Aghanwa et al, 1999). A study done in Nigeria showed that 86% of infertile couples knew about adoption but only 34% of them were willing to consider adoption. This was partly because they wanted a biological child of their own and partly due to a general lack of knowledge and fear of unknown (Omosun & Kofoworola, 2010; Oladokun et al, 2009). Likewise, Nigeria does not have a uniform national policy or legal guidelines for the process of child adoption. Individual states and private adoption organisations have their own guidelines and procedures. This contributes to the misunderstandings and uncertainties for prospective adoptive parents especially when dealing with cases of inter-state adoptions (Oladokun et al, 2009). This leads to confusion and contradictions regarding the rights of the adopting parents and that of the child (Oladokun et al, 2009).

Reproductive health in Nigeria

Reproductive Health (RH) in Nigeria is in a very poor state with some of the poorest statistics in the world. This is made worse by a fast-growing population. According to the National demographic survey, Nigeria is characterised by a high infant mortality rate of 84/1000 live births, as well as high under five (163/1000 live births) and maternal mortality ratios of 576/100,000 live birth (National Population Commission Nigeria and ICF International, 2013; Federal Ministry of Health, 2011). The Nigerian population accounts for only 1.7 % of the total world population but carries 10% of the proportion of maternal deaths globally (Momoh et al, 2015).

Reproductive health for Nigerian adolescents is also grossly deprived. There is a lack of access to sexual reproductive health facilities leaving their sexual and reproductive health needs ignored. This leads to frequent high-risk sexual behaviour, increased incidence of STIs, unwanted teenage pregnancies and unsafe abortions (UNFPA, 2013; UNICEF, 2012; NARHS-Plus, 2012). The majority of unintended pregnancies and unsafe abortions in Nigeria occur among young people leading to fatal complications in three-quarters of young women below 19 years of age and about half of women overall (Momoh et al, 2015; Advocates for youth, 2007). Another common complication of risky sexual health behaviour is that untreated STIs contribute to abnormalities developing in the reproductive tract leading to infertility in both males and females. In fact, untreated STI is the major cause of secondary infertility in the sub-Sahara Africa region with Nigeria central to the infertility belt (Mascarenhas et al, 2012).

Sadly, infertility is not a priority for the Ministry of Health in Nigeria at either federal or state levels. Reasonably, a lot of focus has been placed on maternal and child health, along with communicable diseases such as malaria, tuberculosis and HIV/AIDS in line with achieving the correlated Millennium Developmental Goals (Kana et al, 2015; Federal Ministry of Health-NSHDP, 2010-2015; Nigeria-MDG Report, 2010). However, in the mission statement of the Federal Ministry of Health, it states that it aims to "develop and implement policies and programmes that enhance the standard of living, and improve the quality of life of the Nigerian people and support efficient and effective health services" which includes entirely the various aspects of reproductive health (Federal Ministry of Health, 2019).

The Ministry of Health endorses active community participation. It provides health policies, but relies on private and government institutions, including Non-governmental Organisations for the implementation of health policies and access to services. Infertility treatments in Nigeria are largely the domain of privately established infertility specialist institutions such as *Nordica* and *The Bridge*. Subsidised government specialist hospitals can provide patients with diagnoses and treatment of infertility problems. However, they mostly refer to privately owned specialist hospitals for Assisted

Reproductive Treatments which typically carry a significant financial cost to the patients. For example, a single cycle of IVF at *Nordica Fertility Centre* cost N870,000 (naira), which is equivalent to 4 times the annual average Nigerian wage (Nordica, 2019; Agba & Ushie, 2013).

In Nigeria, the vast majority of Non-Governmental Organisations (NGO) lack the knowledge and cohesive strategies required to effectively develop and advocate reproductive health projects with the federal or state governments of the country (Momoh et al, 2015). Ogbogbou & Idiho (2000) stated the reality of many civil organisations in Nigeria, which do not engage in the development of policies and programmes, as a result of their insufficient knowledge and skills. Many non-governmental organisations in Nigeria operate in isolation from one another instead of developing a unified agenda of promoting reproductive health for all Nigerian people (Momoh et al, 2015).

Psychological issues compounding infertility

Infertility has been established as a global issue. However, people's experience of involuntary childlessness is closely related to where infertility is suffered, and the culture of the perception of infertility in the community where it is being experienced (Burns & Covington, 1999). The desire to have a biological child often leads couples to consider polygamy, extramarital affairs, and divorce as solutions to childlessness (or the lack of a desired gender, usually male), after a prolonged failure of medical treatment. Adoption and fostering are also reluctantly considered as solutions, which comes with own anxiety of the unknown future, especially in traditional African communities.

The desire for a solution at all cost, as well as the economic, social welfare, and public health factors affecting infertility, also has psychological consequences, depending on the ability of those affected to cope mentally. It also motivates infertile patients to practise *reproductive tourism*, a phenomenon whereby infertility patients travel across national or international borders, pursuing medical treatments to facilitate reproduction and parenthood (Inhorn & Patrizio, 2009).

Psychological issues associated with treatment, and treatment outcomes.

Apart from the physical demands and pain of infertility procedures, the attempt by infertility patients, to conceive and deliver healthy babies, can be very demanding psychologically, especially with couples who have had a prolonged history of infertility. The repeated cycles of (failed) infertility treatments for the individual or collectively as a couple, cause a chronic sense of loss, guilt, grief, perceived loss of control, fear of the outcome of future treatments, perceptions of injustice, and social anxiety (Harris & Daniluk, 2010). In spite of these experiences, infertility patients remain persistent in their efforts to achieve a viable pregnancy to deliver a healthy child (Zucker, 1999; Kirkman, 2003; Johansson & Berg, 2005).

The demands of diagnostic investigation, medical treatment and monitoring of infertility, causes infertile patients (especially women), to strongly focus on their body, and its ability to achieving a viable pregnancy, often to the detriment of their emotional, psychosocial and financial aspects of their lives (Harris & Daniluk, 2010). Psychosocial research has shown that IVF and assisted reproductive treatments lead to extreme stress, especially for women. Nevertheless, these women exhibit enormous commitment to achieving at all cost, including, pain, discomfort, health risks, marital discord, and job loss as a result of distractions from normal life and work routines (Remennick, 2000). Studies also show an early increase in prenatal attachment at ultrasound monitoring during fertility treatments. Therefore, the loss of such pregnancy carries a deep sense of grief for what could have been (Seibel and Levin, 1987; Ji et al, 2005). For infertility patients, the relentless physical, emotional and financial investment into successful conception come with an additional high cost: their mental health and wellbeing. Amidst the physical and psychological demands of undergoing and recuperating from medical procedures and schedules, infertile couples may become so caught up on achieving successful treatment that the long term cost implications of treatment are ignored (Mahlstedt, 1985; Cousineau 2006). The imbalanced focus on achieving pregnancy as the infertility outcomes makes it

harder for infertility patients to consider other options such as resolving to adopt, or to remain childless, after failed treatments.

A significant barrier to accessing infertility treatment is cost (Lunenfeld & Van Steirteghem, 2004). Assisted reproductive treatments in LMIC come at very high costs, and are unaffordable for the majority of patients even before the inclusion of travel and accommodation expenses when patients are required to travel out to major cities to receive specialist infertility care (Gerrit, 2012). In spite of the sometimes-severe consequences of infertility in LMIC, infertility remains marginalised because population control policies in reproductive health take precedence, thus infertility patients receive no help toward the costs of their infertility treatments (Nahar and Richters, 2011). Private infertility specialist hospitals are then able to take advantage of the high demand of fertility procedures, coupled with a lack of regulation in cost of infertility treatments, and thereby charge their patients premium prices. The high cost of infertility treatment, together with the physical and emotional demands, place a major strain within relationships, making conception harder to achieve.

Effect of infertility on relationships

Infertility amongst couples is an experience that induces great stress within the relationship. Many couples feel helpless and lacking in control over their lives and health (Galhardo et al, 2011). In many African societies, the ability to procreate is not limited to an individual's aspiration or identity but is seen as a continuum within of the family name, lineage and heritage, making parenthood an important and respected identity (Donkor & Sandall, 2007). Infertility places a great burden on families socially, financially, psychologically as well as affecting individuals' identities in relation to the condition itself and the treatment strategies. Studies also show high rates of marital discord and divorce. This further predispose couples to have unprotected sex with multiple partners leading to further spread of HIV and other STIs (Yusuf et al, 2012).

Apart from affecting couples individually, research shows that the use of gender specific diagnoses have significant effect on couples' relationship.

Female partners of “infertile” men are less likely to experience abuse, marital discord or divorce than their female counterparts; these men are also less prone to being abandoned by their spouses, unlike if they were women (Dhont et al, 2011). In Taiwan, a study showed also that a diagnosis of female infertility came with a higher prevalence of distress and sexual dissatisfaction than amongst husbands diagnosed with male infertility (Lee et al, 2001).

Domestic violence and infertility

Domestic violence as a result of childlessness is very common in many societies where sociocultural accolades are traditionally attached to child bearing. Although it has been reported in both men and women, evidence shows that violence against women as a result of infertility is significantly more prevalent (Watts & Zimmerman, 2002). Violence against women are physical acts of violence toward a female, including sexual coercion, physical threats, psychological abuse, and controlling actions such as physical isolation or restricting access to health care or financial resources (Adeyemi et al, 2005). However, previous studies reveal that men also suffer emotional distress, stigma, verbal abuse, marital instability and loss of social standing, due to childlessness (Dyer et al, 2004). Nevertheless, women bear a greater burden as a consequence of infertility and experience negative and abusive comments, public degradation as well as contempt from in-laws. The combination of infertility and concurrently domestic abuse doubles the threat to their physical and mental health and wellbeing (Okonofua, 2003).

Studies have shown that 70% of infertile women in India experienced violence. This occurred in many forms: physical, verbal, and psychological from their husbands or relatives, especially the in laws (UNISA, 1999). In African societies, domestic violence has been reported in various societies leading to marital instability, infidelity, including the husband taking on another wife (Larsen 1995). In Nigeria, infertile women are susceptible to domestic violence. Domestic violence was reported in 41.6% of women diagnosed with infertility, compared to 11% observed in the general population: thirty-nine percent was attributed to verbal abuse and 17.5% physical abuse (Ameh et al, 2007; Adesiyun et al, 2012).

There is evidence to show that verbal abuse, psychological torture, deprivation of basic needs, and physical violence are the most the frequent forms of domestic violence experienced by infertile women in Nigeria. However, forced sex was less common in infertile women when compared with the general population of women (Ezegwui et al, 2003; Hollos et al, 2003). This differs slightly from a study in Iran by Ardabily et al (2010), which shows that 61.8% disclosed to having experienced domestic violence because of their infertility, where the commonest types in descending order were psychological (33.8%), physical (14%) and sexual (8%), with 6% of the women recounting injuries. In Jamaica, when a woman who does not conceive within a certain period of time after marriage, she is considered a *"mule"* (Family Health International, 2003; Upton, 2001; Mabassa, 2000). In South Africa, such women are called undignified and demeaning terms such as *"sterile cow"* (Family Health International, 2003; Upton, 2001; Mabassa, 2000). However, studies show that with higher socio-economic status or higher education, the prevalence of domestic violence, perceived stigma and infertility induced stress are significantly reduced (Dhont et al, 2011; Donkor & Sandall, 2007).

Ameh et al (2007), suggest that early treatment and prevention of infertility, prompt evaluation, and couple counselling for infertility patients were indispensable to combat the problem of domestic violence, and should be included in the efforts to meet the millennium development goals (Ameh et al, 2007). Domestic violence against infertile women, although significant, remains underreported. Ardabily et al (2010) therefore urges clinicians to be trained to identify the abused women and provide them with medical care and supportive counselling.

Infertility-induced stigma

Stigma is described as a negative sense of social difference from others, outside of the socially defined norm, which is deeply discrediting and devalues the individual (Goffman, 1963). According to Remennick (2000), stigma as a psychological response is determined by the degree of conformity to prevailing culture and norms in a given society. Infertility, as a medical condition and a social state is threatening to the self-esteem and identity of those affected and therefore a source of stigma (Slade et al, 2007). Studies show that the less the

socio-economic standing of an individual within the community, the more devastating the experience of infertility related stigma (Remennick, 2000; Slade et al, 2007). A study by Ofovwe & Agbonataen-Eghafona (2009), identified themes under which the experiences of infertile couples especially women can be categorised. These include 1. *psychological suffering*, 2. *marital instability*, 3. *stigmatisation and abuse*, 4. *social pressure*, and 5. *support and secrecy*. The psychological suffering associated with infertility causes many couples to look for multiple means (sometimes extreme), of finding a "cure" to their infertility. A case study was reported of woman who was an orphan and infertile, and had resorted to creating a fake pregnancy by wearing a calabash in order to escape the psychological trauma, stigma and distress of being seen as an infertile woman in the community, and amongst friends (Adesiyun et al, 2012).

In many African communities, men and women experience infertility-related stigma differently and disproportionately. While women are openly ostracised for their inability to conceive, men still manage to retain their power in the family and the community. Studies show that men perceived themselves as being useful to society despite infertility, because they are economically self-sufficient and have the ability to take care of their family (Dhont et al, 2011). It is socially acceptable for men to take on several wives and multiple sexual partners in order to procreate, even if the cause of infertility is a hidden male factor (Abarikwu et al, 2013; Yusuf et al, 2012). This contributes to the impression that men are able to cope better with infertility in African settings. At the same time, it increases the burden of stigma carried by women, because infertility is perceived socially as "a woman's problem".

For some other couples, secrecy and indifference were identified as coping mechanisms which causes those affected to become "defensive" or act indifferently towards their condition. Ofovwe & Agbontaen-Eghafona (2009) explain that affected couples felt a sense of distrust in discussing their feelings or experiences because of a fear of judgement and/or attracting an unsolicited condolence (Ofovwe & Agbontaen-Eghafona, 2009). People not knowing that they were childless meant that they were less likely to be judged or treated differently in the community. In the same way, if couples pretend like they did

not want (or were not ready) to have children, it shifts the line of reasoning from that of a *perceived disability* due to involuntary childlessness, to a one of an unpopular choice to remain voluntarily childless. These are two different types of stigma, while the first seems helpless and disempowering, the other is perceived as a resolve and therefore less disempowering for the couples affected.

Infertility and religion

While some couples are able to find support from relatives and friends, other patients develop their coping mechanisms through their religious beliefs. Their belief and trust in a higher power that protect human beings and is responsible for what happens to them takes away their burden of guilt; there is solace in the belief that there is a divine reason and eventual good outcome from their experiences (Roudsari & Allan, 2011). On the other hand, others might perceive infertility as "God's punishment for previously committed sins" (Domar et al, 2005). History of premarital sex and previous abortion are perceived to be grievous sins for which the consequence is a delayed conception (Remennick, 2000; Ofovwe & Agbontaen-Eghafona, 2009).

Studies show that spiritual well-being is significantly linked with reduced infertility distress and depressive symptoms in women undergoing infertility treatment (Domar et al, 2005). According to Domar et al (2005), strong religious beliefs may help or interfere with coping and healing. For example, belonging to a religious group may alleviate symptoms of anxiety and depression by inducing relaxation through prayer, and prevent social isolation for those affected. However, it can also aggravate the patient further through the disappointment of unanswered prayers, leading to anxiety and depressive disorders, and finally social dysfunction and isolation. Either way, religious beliefs have a significant effect on the health and wellbeing of infertility patients and should be considered carefully during infertility management.

Infertility and sexual dysfunction

Sexual dysfunction is a problem affecting both males and females, irrespective of sexual orientation, that can potentially interfere with the initiation, consummation, and/or satisfaction with sex, by hindering the desire, excitement, orgasm, and resolution phases of the human sexual

response cycle (Natarajan & Khan, 2018). The psychological impact of infertility can cause a significant strain in relationships, which has a ripple effect on all aspects of the life of affected men and women, including their sexual function and relations. Infertility is, to some extent an indication of their sexual identity and abilities (Andrew et al, 1992; Jamali et al, 2014).

Studies show that sexual disorders are prevalent among female infertility patients, and that women diagnosed with infertility were at a higher risk of having sexual dysfunction, when compared with women without infertility (Millheiser et al, 2010; Keskin et al, 2011; Winkleman et al, 2016). Bringhenti et al (1997), also reported that women with infertility undergoing IVF treatment recounted lower marital satisfaction than women with children, recruited at routine gynaecologic examinations. Similarly, in men with infertility, erectile dysfunction, dysfunction in arousal-sensation and arousal-lubrication was found to be elevated, when compared to the normal male population (Khademi et al, 2008). It was also found that among male partners who knew they were the cause of the inability to conceive, there was a lower sexual and personal quality of life, when compared with male partners of couples without an assumed male factor infertility (Smith et al, 2009). According to Wischmann (2010), sexuality and the desire for a child are strongly interconnected, therefore counselling for infertile couples should include some form of sexual therapy.

Sexual dysfunction amidst couples has the potential to cause anxiety, depression, marital discord and abuse amongst partners in a relationship. In the same way, infertility can create a *"sex on demand"* situation. This is where there is a specific collection a semen sample for semen analysis and/or sperm preparation and insemination, or planning intercourse in a monitored natural cycle. All of these create a burden for the patient, impeding their sexual desire and satisfaction (Natarajan & Khan, 2018). These have negative connotations for the mental and psychological health, as wells as their social relations as sexual partners, placing further unwanted pressure on their reproductive health.

Depression, anxiety and infertility

Researchers have identified a high prevalence of psychiatric disorders in women being treated for infertility. In one study of 112 women, 40.2% of those receiving treatment for infertility have a diagnosed psychiatric disorder (Chen et al, 2004). Generalized anxiety disorder was the most commonly diagnosed (23.2%), followed by major depression (17.0%) and 9.8% who have dysthymic disorder (Chen et al, 2004). The levels of anxiety and depression in infertile women are equivalent to the ones found in women with heart disease, cancer and women who are HIV positive (Domar et al, 2000). A study by Galhardo et al, (2011) showed that Portuguese couples with an infertility diagnosis, seeking treatment in infertility public and private clinics, presented with significantly higher scores for depression, external and internal shame, when compared with normal controls and couples who were adopting. The infertile couples also had lower scores for acceptance and self-compassion. This was in comparison with couples adopting who had better coping skills and used an objective and rational approach (Galhardo et al, 2011). In Nigeria, a study conducted to determine the level of psychological distress amongst males with infertility found that 28% of the men were psychologically distressed, 17% suffered depression and 11% had a generalised anxiety disorder (Yusuf et al, 2012). In this study, 25% of the men had a history of marital discord leading to divorce for no reason than infertility. The prevalence of psychological distress in women presenting with infertility varies from 48% to 98% (El-Kissi et al, 2012). Within couples, women experienced a higher prevalence of psychological distress, thought to originate from attitudes and consequences of infertility (El-Kissi et al, 2012). The perception that conception and childbirth was the responsibility of a woman created a psychological burden due to delay; thus psychological disorders such as general psychological malaise, depression, anxiety and low self-esteem were all noted amongst these group of women (El-Kissi et al, 2012). An interesting study in Japan found that the knowledge of the male partner's infertility reduced anxiety and depression scores on the HADS scale when compared with women who had no knowledge (Ogawa et al, 2011). This demonstrates that the burden of guilt of a person contributes largely to the psychological

morbidities experienced by infertility patients especially when the identified or perceived cause of infertility lies with that person.

Testing for Anxiety and Depression in Clinical Settings

A psychological test is a set of stimuli administered to an individual or a group under standard conditions to obtain a sample of behaviour for assessment (Silverman, 1990). According to Silverman (1990), there are two types: objectives and projective tests. Objective tests require the client to make specific responses to closed questions, typically "yes or no", "true or false", or ordinal responses as found in a Likert scale. A projective test on the other hand allows the client to respond to open questions in their own words.

Most psychological test outcomes are subjective because the tests are just as good as the skill of the person administering the test (Silverman, 1990). In cases where psychological testing tools are self-administered, the interpretation of the test depends largely on what the respondent perceives as the true representation of their current state, especially within a list of options. Currently, there are no laboratory or clinical biomarkers to reliably diagnose anxiety or depression. Thus, the clinical diagnosis is dependent on asking questions using specific tools and psychological tests to answer clinical question that otherwise not easily be answered through direct observation, clinical interviews or consultations (Richardson & Puskar, 2012). Psychologic tests, however, are usually given as a part of other tests because no one test is sufficient to answer the complex questions especially in clinical settings (Silverman 1990). Furthermore, the choice of assessment tool is influenced fundamentally by the personal preference of the physician as well as the practicality of the chosen tool within the clinical setting (O'Connor et al, 2009; USPSTF, 2009). Irrespective of the chosen tools, it is generally recommended that the tool for assessment should be concise, accurate, user friendly, easy to read, self-reported, easily integrated into clinical practice, and freely available (Richardson & Puskar, 2012)

In primary care, depression and anxiety are common amongst attending patients but are often missed and left untreated as focus is placed on the biomedical aspect to the patient's signs and symptoms (Richardson &

Puskar, 2011). Psychological assessments can be given as part of other diagnostic tests within a clinical setting but it is important for physicians to consider when it is appropriate to use it to assist or rule out a diagnosis definitely and/or a medical intervention (Silverman, 1990). Similarly, patients may be unaware of anxiety or depression symptoms, which may partially explain their slow response to treatments despite multiple tests and treatments, including non-adherence to treatments (Burton et al, 2011). Additionally, anxiety and depression, when left untreated can result in other health problems in the cardiovascular, endocrine and immune systems (McEwan, 2009). Likewise, patients with chronic illness commonly develop anxiety and depressive disorders (Katon, 2011). The World Health Organisation (WHO) predicts that by 2020, depression will be the second largest cause of disability worldwide after cardiovascular diseases (Kessler et al, 2009).

In the United Kingdom, the National Institute for Health and Care Excellence –NICE (2009) recommends routine screening for depression among patients with chronic health conditions such as heart disease and diabetes mellitus. Similarly, the United States Preventive Services Task Force (USPSTF, 2009) recommends screening for patients with chronic health conditions, provided that health services are available to diagnose, treat, support and follow up those who screen positive. However, routine screening in a primary care setting may produce false negative and false positive results; the latter being more common in clinical and primary care settings; this can lead to undue and distressing labelling of patients (USPSTF, 2009). Therefore, initial screening test should be followed by full diagnostic testing using the Diagnostic & Statistical Manual, Fourth edition (DSM-IV) criteria, along with immediate treatment (Richardson & Puskar, 2012). These together significantly lower clinical morbidity of depressive disorders.

Short screening tools for common mental disorders in Nigerian general practice

Assessment of anxiety and depression cannot be measured using laboratory tests, thus the only way to evaluate patients for anxiety and/or depression is by asking questions (Richardson & Puskar, 2012). Examples of

such depression and anxiety tools used in primary care are shown in table 2.4. Tools for psychological and/or psychiatric assessment should be concise, precise, simple to administer, self-reporting, easily available, and simple to intergrate into normal, clinical practice (Sánchez-López & Dresch, 2008; O'Connor & Parslow, 2010; Richardson & Puskar, 2012; Makanjuola et al, 2014).

Research shows 33-79% of patients suffering from psychiatric illness are missed during consultations in general practice and primary care settings (Freelings et al, 1985; Higgins, 1994). Similarly, in Nigeria, a 1995 study found that 55.1% of mental health conditions were identified in typical primary care settings (Ustun & Sartorious 1995). In Nigerian general practice, depression & anxiety disorders are not routinely investigated; this is despite research evidence showing that the routine use of screening tools for psychological distress improved identification by health workers in such settings (Higgins, 1985; Christensen et al, 2005; Makanjuola et al, 2014; Iheanacho et al 2015).

NICE (2016) recommends that patients showing signs or symptoms of depression, especially those with history of chronic illnesses, should be asked two initial question to establish the possibility of an ongoing depressive disorder. It also recommends that in providing treatment and care, patients' needs and preferences should be considered carefully (NICE, 2016). The initial two questions are:

1. *During the last month have you been feeling down, depressed or hopeless?*
2. *During the last month have you often been bothered by having little interest or pleasure in doing things?*

If the answer is 'yes' to either questions, three further questions should be asked; these are- *During the last month, have you often been bothered by:*

1. *Feelings of worthlessness?*
2. *Poor concentration?*
3. *Thoughts of death?* (NICE, 2016)

There are also tools that can be used in busy clinical setting to screen for common mental disorders. In Nigeria, some mental health screening tools have been used and validated for primary health care and general practice. These tools include:

1. K6:

The K6, a screening questionnaire developed by Ron Kessler, is a six-item scale of non-specific psychological distress used in many national health surveys to screen and measure the severity of mental health problems (Kessler et al, 2002; Mitchell & Beals, 2011). It is developed to be administered by a lay interviewer and available in English and Japanese versions; it was also included in the Nigeria survey of mental illness and wellbeing (Kessler et al, 2002; Gureje et al, 2006; Furukawa et al, 2008). This tool was designed to be sensitive at the approximate level for the clinically significant distribution of psychological distress (Makanjuola et al, 2014). Although non-specific, it augments the ability to separate cases of serious mental illness from non-cases due to its scalar assessment. Thus, it gives more information, allowing improved treatment advice (Kessler et al, 2002; Mitchell & Beals, 2011).

2. Composite International Diagnostic Interview (CIDI):

The CIDI is a comprehensive, well-structured interview designed to be used by individuals without clinical training. It is used for the assessment of mental conditions in epidemiological, clinical and research conditions (Kessler & Ustun, 2004). It was developed according to the definitions and criteria of the International Classification of Diseases, 10th Revision, and the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition- DSM-IV (Makanjuola et al, 2014). The CIDI was a fundamental tool used in the World Mental Health Survey and the depression and generalized anxiety disorder segments of CIDI are utilised by researchers as the gold standard for psychiatric diagnosis (WHO, 2004; Kessler et al, 2004; Makanjuola et al, 2014). The CIDI is 86% specific and 29% sensitive for Generalized Anxiety Disorders (GAD), and 69% specific and 92% sensitive for Major Depressive Episodes (MDE) (Peters & Andrews, 1995).

3. Patient Health Questionnaires (PHQ)

The PHQ-2 is a simple initial screening tool for depression. It consist of 2 questions based on the DSM-IV text revision (American Psychiatric Association, 2000). The questionnaire is self-administered and a response of *"no"* to both questions indicates unlikely depression and no further action required (Kroenke & Spitzer, 2002; Richardson & Puskar, 2012). On the other hand, a positive answer to one or both of the questions is sensitive and detects over 90% of major depression cases (Richardson & Puskar, 2012). The PHQ-2 contains first 2 items of the PHQ-9 which are listed below (Kroenke et al, 2003):

Over the last 2 weeks, how often have you been bothered by any of the following problems?

1. *Little interest or pleasure in doing things*
2. *Feeling down, depressed or hopeless*

The PHQ-2 score severity ranges from 0-6; it is 83% sensitive and 92% specific at the score level of 3 or more (Kroenke et al, 2003). This makes it a valuable measure of depression especially in busy clinic settings. However, PHQ-2 results should be followed up by a PHQ-9 because the PHQ-9 includes the entire 9 symptoms required to establish a diagnosis of depressive disorder according to the DSM-IV (Kroenke et al, 2003). PHQ-9 is 88% sensitive and 88% specific (Kroenke et al, 2001; Matthews et al, 2002; Gilbody et al, 2007; Wittkampf et al, 2007). The PHQ-9 questionnaire as indicated consists of 9 questions which assess depression symptoms with four answers ranging from *"not at all"* to *"nearly every day"*. From this finding, scores range from 0 to 27 (Kroenke et al, 2010). A difference in a patient's PHQ-9 test score of 5 indicates remission and a difference of 10 indicates partial response to intervention when repeated usually a month later (Richardson & Puskar, 2012). This makes the PHQ-9 valuable, not only diagnosis of depressive disorders, but also as a monitoring tool for disease progression or remission.

PHQ scales have been validated and translated into over 60 languages, making it very useful globally and indicated mainly for depression, mixed

anxiety and depression (MAD) as well as seasonal affective disorders (SAD) (Kroenke et al, 2010).

4. 12-Item General Health Questionnaire- GHQ12

The GHQ 12 was originally developed in UK in 1979 by Goldberg and his associates as a screening questionnaire for assessing the presence of psychological morbidities in various clinical and non-clinical settings (Goldberg et al, 1997; Gelaye et al, 2015). Since its inception, it has become well-known and widely validated screening questionnaire. It has been shown to be reliable and valid in the measurement of psychological distress and general wellbeing, and has been translated into nearly 40 languages (Alexopoulos et al, 1988; Goldberg et al, 1997; Lindo et al, 2006; Shelton & Herrick, 2009). Although the GHQ 12 was originally designed for use in an adult population, many studies have used it in adolescents and educational settings because of its conciseness, consistency and cross-cultural validity (Werneke et al, 2000; Gelaye et al, 2015).

According to Gelaye (2015), the psychometric properties and factor analysis of the GHQ12 as a tool indicates its effectiveness for identifying anxiety, depression and social dysfunction across diverse cultures worldwide. The GHQ-12 is a self-administered tool that is short, easy to complete and score in a variety of ways, thus making it beneficial for providing multiple outcome measures (Lindo et al, 2006). The GHQ 12 can be scored in three ways: the original scale [0-0-1-1], the Likert scale [0-1-2-3] and the chronic scale [cGHQ] (Goodchild & Duncan-Jones, 1985; Goldberg & Williams; 1988). The different scores that result from the different scoring methods has an impact on the reported prevalence of depression across population studies as the differing scales can produce conflicting levels of depression. It is important therefore to validate the scale in every setting prior to its use (Gureje & Obikoya, 1990; Martin & Jomeen, 2003; Shelton & Herrick, 2009; Makanjuola et al, 2014).

Nevertheless, higher thresholds may be required to identify cases because higher GHQ scores are to be expected as a complication of the symptoms of physical illnesses (Goldberg & Williams, 1988; Jackson, 2006;

Shelton & Herrick, 2009). According to Romito et al (1999), who recommend that "the GHQ-12 can be used and should be preferred in all clinical settings for screening and case detection" of psychological conditions. In addition, GHQ functions properly in different societies irrespective of their social or economic developmental status and only loses an insignificant amount of meaning by translation into other languages (Goldberg et al, 1997).

Studies have been documented evaluating and validating the GHQ-12 tool and its psychometric properties which have been used amongst the Yoruba speaking people of Nigerian as well as a literate population in Kenya, among others (Gureje & Obikoya, 1990; Gureje, 1991; Abubakar & Fischer, 2012). It shows that the GHQ 12 factorial structure and psychometric properties measured in different cultural backgrounds permits for the confirmation validity in new cultural contexts, in addition to allowing the comparisons between cultural settings as to whether or not mental health symptoms are distributed similarly throughout different cultural contexts (Gureje, 1991; Abubakar & Fischer, 2012).

Drug Treatment for Anxiety and Depression associated infertility

Antidepressants are psychotropic drugs for the treatment of a spectrum of depressive syndromes, including anxiety disorders and obsessive–compulsive disorder (Benkert et al. 2001). There are different types of anti-depressants, the most common which are the selective serotonin reuptake inhibitors (SSRI), serotonin-noradrenaline reuptake inhibitors (SNRIs), noradrenaline and specific serotonergic antidepressants (NASSAs) tricyclic antidepressants (TCAs), and monoamine oxidase inhibitors (MAOIs) (NHS UK). The most widely used anti-depressant is the SSRI, due to their fewer side effects, when compared to the other classes of antidepressants. However, there is evidence to show that the use of antidepressants influences changes in the Hypothalamic-Pituitary-Ovarian (HPO) axis, which controls the hormonal balance for menstruation and reproductive system feedback mechanism, causing HPO axis dysfunction (Timby et al, 2011). The HPO dysfunction leads to anovulation or luteal phase defects, and may thereby inhibit a woman's ability to conceive naturally (Casilla-Lennon et al, 2016).

Table 2.4: Depression & Anxiety Tools used in Primary Care (Richardson & Puskar, 2012)

	Items to answer	Self-report	Time to administer (in minutes)	Available in Public Domain
Depression				
PHQ-2	2	Yes	Less than 1	Yes
Zung Self Rating Depression Scale	20	Yes	10	Yes
Becks Depression Inventory	21	Yes	6-10	No
Hamilton rating Scale for Depression	17	No	20	Yes
Centre for epidemiologic Studies- Depression Scale	20	Yes	5-7	Yes
PHQ-9	9	Yes	2	Yes
Special Populations				
Geriatric Depression Scale (Short version)	15	Yes	10	Yes
The Cornell scale for Depression in Dementia	19	No	20	No
Edinburgh Postnatal Depression scale.	10	Yes	5	Yes
Anxiety				
Single Question Screening	1	Yes	Less than 1	Yes
Zung Self-Rating Anxiety Scale	20	Yes	10-15	Yes Professional use
Hamilton Anxiety Scale	14	No	10-15	Yes
GAD-7	7	Yes	2-3	Yes

Psychological interventions for infertility management.

Boivin (2003) reviewed the effectiveness of psychosocial interventions for infertility in terms of improved psychological well-being, increase in pregnancy rates, and the effective of one intervention over others. While the findings showed pregnancy rates were unlikely to be affected by psychosocial interventions, patient wellbeing was significantly improved with men and women equally benefitting from the psychological interventions (Boivin, 2003). Boivin (2003) suggested that there was not enough evidence to recommend psychological interventions or counselling, but that further research is required to determine which psychological intervention works best for different groups of patients and at what time optimum effectiveness is observed for infertility patients.

Educational therapy and psychoeducation:

Psychoeducation is the process of providing education and information to those needing or receiving mental health services. Knowledge enables and empowers people to make better choices and decisions regarding their health. Psychoeducation had been used for people diagnosed with mental health conditions, life-threatening or terminal illnesses, and in infertility-related psychological distress. Educational therapies and psychoeducation involve patients and their relatives in therapy sessions, and by so doing, they are empowered to understand and accept the illness and cope with it in a successful manner (Baüml et al, 2006). In infertility psychoeducation, the focus is placed on training participants on ways to of coping and preventing infertility induced stress through interventions such coping training, stress reduction, sex therapy and obtaining information about infertility medical tests or treatments (Boivin, 2003).

Cousineau et al, (2008), carried out a study to develop and test a concise, cost-effective online education and support program for female infertility patients. The research found that the women felt more informed about making decisions regarding their treatment, with an improvement in

their social concerns and sexual concerns, thereby experiencing a reduction in the prevalence of infertility related stress (Cousineau et al, 2008).

Supportive Psychotherapy

Supportive psychotherapy focuses on problems and conflicts that the patient is aware of, and allows the patient to set the course of the treatment (Markowitz, 2014). According to Markowitz (2014), evidence-based therapies, such as cognitive-behavioural therapy (CBT) and interpersonal psychotherapy (IPT), technically fall under the supportive psychotherapy umbrella. For infertility patients experiencing psychological distress, this has the potential to generate a sense of control and empowerment that could stimulate the ability to recognise unhealthy thoughts and behaviour. Psycho-social support can also lead to satisfaction with infertility treatment methods by developing and improving the coping strategies of infertility patients, as well as causing a decrease in anxiety levels among couples undergoing infertility treatments (Wischmann et al, 2001; Noorbala et al, 2009).

Interpersonal psychotherapy (IPT)

Interpersonal therapy (IPT), is a structured, time-bound psychotherapy, used in the treatment of major depressive disorders (Weissman et al, 2000). The role of the therapist is to assist the patient to recognise associations between being depressed and interpersonal incidents, by focusing on one or more of the interpersonal problem areas which are: role dispute, role transition, or interpersonal deficits and grief (de Mello et al, 2001). Interpersonal psychotherapy focuses on interpersonal stressors, therefore is an ideal treatment for infertility-related depression (Koszycki et al, 2012). Infertility-related stress, in its social context, is precipitated by interpersonal interactions, conflicts, social isolation, and stigmatising events that may occur in the family and/or the community as a result of childlessness. (Hunt and Monach 1997). The lack of social support has been found to worsen infertility related stress for infertility patients, perception of stigma and poor psychological response to infertility treatments (Mindes et al, 2003; Slade et al. 2007; Verhaak et al, 2010; van Empel et al, 2010; Martins et al, 2011).

A pilot study by Neugebauer et al (2006; 2007), showed the efficacy of a modified counselling intervention based on IPT, in reducing depressive symptoms among non-clinically depressed women with a history of miscarriage. In pregnant and postpartum women, IPT has been found to be the antidepressant intervention of choice (Mulcahy et al, 2010; Klier et al, 2001; O'Hara et al 2000). IPT is ideal for management of psychological morbidities associated with infertility because it focuses on strengthening social supports (Koszycki et al, 2012).

Cognitive Therapy

Although depression, anxiety and psychological conditions usually begin early in life, the symptoms tend to be self-managed until a level is reached whereby coping skills decline and symptoms emerge which often go unrecognised in primary care settings (Richardson & Puskar, 2012). For many patients presenting to clinicians and other health workers primary care, choice and preference is based on location, familiarity, patient-clinic relationship, convenience or reduced stigma giving the opportunity for health worker to build relationships through direct listening and supportive therapy (Richardson & Puskar, 2012)

According to Beck's Theory of Depression (1976), personal events may contribute to depression by creating underlying unhealthy beliefs in relation to self, others, and the humanity which tends to resurface when stressors are triggered (Blenkiron, 1999; Richardson & Puskar, 2012). Epictetus, a Greek philosopher said over 200 years ago that 'people are not disturbed by events but the view they take of them' (Blenkiron, 1999).

Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) endeavours help individuals recognise, address and correct inaccurate and often unhealthy beliefs and thoughts; replacing them with positive helpful, healthy thoughts beliefs and behaviour. It is a structured, problem-oriented intervention that is focused on solving a present problem and has become a treatment of choice for various mental health conditions (Blenkiron, 1999; NICE, 2006; O'Hanlan, 2006; Rupke et al, 2006; NICE, 2009). The effectiveness of CBT has been

demonstrated in primary care in dealing with depression and anxiety disorders, even when compared with other psychological interventions for patients (Hunot et al, 2007; Cape et al, 2010). CBT is most effective with motivated clients who are willing to engage and participate in the process of identifying and correcting negative unhealthy thoughts and behaviour (Blenkiron, 1999; Richardson & Puskar, 2012).

Amongst infertility patients, CBT proved to be of better benefit than pharmacological treatment of infertility related depression, improving the patient outcomes up to 79.3% of patients (Berga et al, 2003; Faramarzi et al, 2008; Buck-Louise et al, 2014). Counselling in infertility (as in other bio-psychological impairments such as cancer) offers the opportunity to explore, discover and clarify ways of living more satisfyingly and resourcefully when fertility impairments have been diagnosed, offering a pathway to reducing the stress levels of the inflicted even when the cause of infertility is unknown (Van den Broeck et al, 2010; Facchinetti et al, 2004). CBT has also been found to reduce infertility-associated stress in patients undergoing IVF treatment, even after failed IVF episodes (Peterson & Eifert, 2011; Facchinetti et al, 2004).

Health workers gain the influence and trust of their patients and can through discussions provide health education, guidance support and reassurance to patients about their mental health and infertility treatment options; while providing a lifelong skill that can be transferable to other aspects of their life in future (McLeod & Clemency, 2011; Richardson & Puskar, 2012; Rahman et al, 2014).

Conclusion

In conclusion, infertility is a condition that affects patients not only physically, but mentally, psychologically, and socio-economically. Its management should therefore be treated as such. Therefore, there is the need to develop a culturally appropriate intervention, specifically designed to tackle infertility-related psychological distress.

In the following chapter (3), the process of determining the prevalence of psychological morbidities associated with infertility in 2 Nigerian hospital settings is described in details. In addition to this in Chapter 4, an intervention

for the management of infertility-related psychological distress was developed based on the Thinking Healthy Programme (WHO, 2015). This novel intervention is being designed for use within resource-poor African settings. The details will be discussed in Chapter 4.

Chapter 3:
A cross sectional study of the prevalence of psychological morbidities associated with infertility in 2 Nigerian hospitals.

Introduction

In many African communities, high levels of infertility continue to co-exist with high fertility rates for reasons which are derived from cultural, socio-economic and medical factors (Okonofua et al, 1997; Mascarenhas et al, 2012). The high fertility rate is a source of concern to those affected; it also gains a lot of attention from stakeholders and policy makers who are willing to provide help for those who wish to control their fertility (UN Millennium Project, 2005; Grollman et al, 2018). The high infertility prevalence is also a source of major concern for those affected, who are willing to go to any lengths to conceive and give birth to live and healthy babies (Shahin, 2007; Ombelet et al, 2008; Gerrits & Shaw, 2010). Although infertility has had major medical breakthroughs in its management as a medical condition, this comes usually at a very high cost physically, mentally and financially. It also comes with little support from national governments and international donors (Conolly et al, 2010; Akinloye & Truter, 2011; Wu et al, 2013). Infertility accounts for more than half of patients seen in gynaecological clinic in African countries, usually associated with sexually transmitted infections (STI), pelvic inflammatory diseases (PID) and the use of unsafe abortion practises within the region (Mascarenhas et al, 2012; Okonofua, 2002; Araoye, 2003; Larsen, 2000; Gerias & Rushwan, 1992).

Infertility places a huge personal and social burden on those affected. This can result in high levels of anxiety, depression, social dysfunction, sexual dysfunction, and domestic violence in the home; all of which have further negative effects on their reproductive health (Ardabily et al, 2011; Antai & Antai, 2008; Castro et al, 2008 Dutton & Nicholls, 2005; Xu et al, 2005). For example, an Iranian study by Ardabily et al (2011), found that the rate of domestic violence against women with female factor infertility was 61.8%.

Furthermore, the high financial costs of infertility treatments and assisted reproductive techniques (ART) makes receiving care inaccessible to all but the rich few, especially in low and middle income countries (Ombelet et al, 2008; Sembuya, 2010; Rouchou, 2013). Verhaak et al. (2007) propose 3 ways in which infertility treatment result in stress: chronic stress caused by the threat of infertility and loss of hope, stress from the outlook of the treatment itself and stress from participation in the treatment. All combine to place a huge psychological burden on patients with infertility. Whilst this has been quantified in western settings, there are few assessments in African settings.

This study is a cross sectional survey of patient attending infertility clinics in two major hospitals in Nigeria. The study was carried out to determine the prevalence of psychological morbidities amongst patient attending for infertility treatments. Data was collected at two Nigerian tertiary referral hospitals: the National Hospital Abuja, and University College Hospital, Ibadan.

Specific Objectives:

1. To determine the prevalence and correlates of psychological morbidities amongst patients attending the fertility clinic at the National Hospital Abuja (NHA), in Nigeria

2. To determine the prevalence and correlates of psychological morbidities amongst patients attending the fertility clinic at University College Hospital (UCH) Ibadan, in Nigeria.

Research Questions

1. What is the prevalence of psychological morbidities amongst patients attending infertility clinics for treatment at NHA and UCH, Nigeria?
2. What factors are associated with psychological morbidities amongst patients attending infertility clinics for treatment at NHA and UCH, Nigeria?

Materials and Methods

Patients attending the National Hospital Abuja (NHA) and University College Hospital Ibadan (UCH) in Nigeria were recruited for this study. Participants were sampled using a convenience sampling method. Patient were recruited as seen at the infertility clinics located at both hospitals. Patients attending the infertility outpatient clinics include those attending for the assisted reproduction, and other gynaecological, andrology and nephrology diagnoses and management relating to infertility. These patients were approached and given a written document that contained information about the research participant information sheets (PIS).

Those who consented to participate in the research were asked to complete and sign the informed consent forms (ICF). The PIS and ICF forms were produced in both English and Yoruba. Nigeria has a population of 180 million people with over 250 ethnicities, languages and dialects (Coleman 1958; Blench & Dendo, 2003; Ukiwo, 2005). As a previous British colony country, the official language is English language. The NHA is in Abuja, a capital city created due to its geographical central location on the Nigeria map. Its population consists of people from many different dialects and ethnicities, and English and Pidgin English are most commonly spoken by all ethnicities. UCH on the other hand is in Ibadan, a city located in the south west region of Nigeria. The commonly spoken languages in this area are Yoruba and English. As a requirement for ethical approval at UCH, all external documents for participants were submitted in both English and Yoruba. At both NHA and UCH, translators were available for participants to interpret into relevant languages. The translators were however not engaged, as all participants were able to complete their questionnaires, and communicate in English language.

Following consent, participants were given a questionnaire to complete with questions on demographics, information of their infertility history, and information about relationships with the spouse, family and friends. They also completed the GHQ 12 questionnaire. The responses are self-reported, but assistance was readily available to those who required explanation or translation.

GHQ12 Scoring

The GHQ is a tool used to measure current mental health. It was developed by Goldberg (1970), originally as a 60-item questionnaire. Shorter versions such as the GHQ-30, GHQ-28, GHQ-20, and GHQ-12 have been developed (Goldberg 1972; 1978; Goldberg & Hillier, 1979; Goldberg et al, 1997). The GHQ tool has been validated in many languages, and used widely within various settings and cultures (Ali et al, 2016; Cuéllar-Flores et al, 2014). The GHQ12 is particularly effective for use in busy clinical settings as a concise, uncomplicated, user friendly screening tool which has been applied successfully in diverse research settings (Jacob et al, 1997; Schmitz et al, 1999; Pevalin, 2000; Donath, 2001).

The GHQ 12 is well-known and widely validated screening questionnaire. It has been shown to be reliable and valid in the measurement of psychological distress and general wellbeing, and has been translated into nearly 40 languages (Alexopoulos et al, 1988; Goldberg et al, 1997; Lindo et al, 2006; Shelton & Herrick, 2009). According to Gelaye (2015), the psychometric properties and factor analysis of the GHQ12 as a tool indicates its effectiveness for identifying anxiety, depression and social dysfunction across diverse cultures worldwide. The GHQ-12 is a self-administered tool that is short, easy to complete and score in a variety of ways, thus making it beneficial for providing multiple outcome measures especially in busy clinical settings (Lindo et al, 2006).

The GHQ uses a scale which questions the participant about certain existing behaviours or symptoms. The response to each question (item) is ranked on a four-point scale: less than usual, no more than usual, rather more than usual, or much more than usual. The GHQ-12 has a maximum score of 36 or 12 depending on the chosen scoring method. Usually, scoring methods are Likert scoring (0-1-2-3), or bi-modal (0-0-1-1). For the purpose of this research setting, the bimodal scoring method was employed (Goldberg & Williams, 1988; Gureje et al, 1990; Abiodun, 1993; Abiodun, 1994).

Table 3.1: Table showing GHQ12 Questionnaire and scoring (Goldberg, 1979).

1. Have you recently been able to concentrate on what you're doing?			
0-Better than usual	0- Same as usual	1-Less than usual	1- Much less than usual
2. Have you recently lost much sleep over worry?			
0- Not at all	0- No more than usual	1- Rather more than usual	1- Much more less than usual
3. Have you recently felt that you are playing a useful part in things?			
0- More so than usual	0- Same as usual	1- Less so than usual	1- Much less than usual
4. Have you recently felt capable of making decisions about things?			
0- More so than usual	0- Same as usual	1- Less so than usual	1- Much less than usual
5. Have you recently felt constantly under strain?			
0- Not at all	0- No more than usual	1- Rather more than usual	1- Much more less than usual
6. Have you recently felt you couldn't overcome your difficulties?			
0-Not at all	0- No more than usual	1- Rather more than usual	1- Much more less than usual
7. Have you recently been able to enjoy your normal day to day activities?			
0- More so than usual	0- Same as usual	1- Less so than usual	1- Much less than usual
8. Have you recently been able to face up to your problems?			
0- More so than usual	0- Same as usual	1- Less so than usual	1- Much less than usual
9. Have you recently been feeling unhappy or depressed?			
0- Not at all	0- No more than usual	1- Rather more than usual	1- Much more less than usual
10. Have you recently been losing confidence in yourself?			
0- Not at all	0- No more than usual	1- Rather more than usual	1- Much more less than usual
11. Have you recently been thinking of yourself as a worthless person?			
0- Not at all	0- No more than usual	1- Rather more than usual	1- Much more less than usual
12. Have you recently been feeling reasonably happy, all things considered?			
0- More so than usual	0- Same as usual	1- Less so than usual	1- Much less than usual

The presence or absence of a psychological morbidity was measured using a GHQ12 score of 3 or more as the cut-off point of the presence of psychological "caseness". The cut off 3 was chosen for several reasons. First, according to Goldberg et al (1997), different validity studies of the GHQ 12 have produced different recommended cut off points in various population

and within different Nigerian populations. However, at the cut-off point of 2/3, the results produce high levels of sensitivity and specificity (Table 3.2).

Table 3.2: Cut off points for GHQ12 in various Nigerian populations according to validity studies (Goldberg et al, 1997)

Authors/Date	Setting	N	Threshold	Sensitivity (%)	Specificity (%)
Gureje & Obikoya, 1990	Nigeria	214	0/1	67.0	74.0
Abiodun, 1993	Nigeria	272	3/4	83.7	79.8
Abiodun, 1994	Nigeria	263	2/3	88.7	83.3

Coker et al (2013) examined the co-morbid psychiatric disorder among women attending a family planning clinic in Lagos, Nigeria and used a cut off of 2 to determine psychological caseness. However, Goldberg & Williams (1988) highlight that high scores are more common in those with pre-existing physical illness or in patients expected to have somatic illness or social dysfunction. They propose that when differentiating between cases and non-cases in populations with pre-existing illness, the threshold should be raised to obtain optimal results (Goldberg & Williams, 1988). We therefore chose 3 as the cut off to account for underlying condition of infertility.

Domestic Violence Questionnaire

Domestic violence is a term which refers to a wide range of physical, sexual, emotional and financial abuse of people who are, or have been, intimate partners (DoH, 2000). Domestic violence as a result of childlessness has been reported in both men and women, but evidence shows that violence against women as a result of infertility is significantly more prevalent (Watts & Zimmerman, 2002). In a Greek study, about 32.5% of women reported to have suffered from violence throughout their lives with 5.0% of women reported to have started experiencing violence after infertility was diagnosed (Ozturk et al, 2107). A Nigeria study on the other hand showed intimate partner violence prevalent amongst 31.2% of women with unemployment and prolonged duration of infertility (Aduloju et al, 2015). Verbal abuse,

psychological torture, deprivation of basic needs, and physical violence are the most the frequent forms of domestic violence, with forced sex amongst infertile women being less common in Nigeria (Ezegwui et al, 2003; Hollos et al, 2003).

Perpetration of infertility-related domestic abuse in African societies is not only limited to the spouse. Abuse come in many forms from the extended family of the spouse within the same household (Mabassa, 2000; Upton 2001). In Nigeria, enactment of domestic violence associated with infertility is not limited to the spouse. Extended family members may use their hierarchy in the family to enact abuse when a desired pregnancy is delayed. A study by Ameh et al (2003) in Zaria, Nigeria, showed that domestic abuse as a result of infertility came predominantly from husbands (34%) and female in-laws (26%).

For this reason, the term '*domestic violence'* is used in this study, rather than '*intimate partner violence*' which could exclude other significant perpetrators of infertility-related psychological distress as a result of abuse. Domestic violence is a significant contributor of psychological morbidities associated with infertility in Nigeria, thus determining its prevalence is important for this study.

Sampling

This study on its own sought to determine the prevalence of psychological morbidity amongst patients attending the clinics for infertility treatments. It also served as a platform to screen for patients who would be eligible for recruitment into an external pilot trial testing an intervention to manage the psychological problems identified. According to Ukpong & Orji (2006), the prevalence of psychiatric morbidity in a similar population was 46.4% amongst infertile women using a GHQ questionnaire. Based on this knowledge, it was calculated that 150 patients were required to participate in the cross-sectional study/ screening in order to gain the number of patients testing positively, who will be offered recruitment into the external pilot RCT.

Sample Size Determination for Cross sectional Study

The sample size for the study will be determined using a sample size determination formula by Kirkwood (1988).

$$n = \frac{2(Z_\alpha + Z_\beta)^2 \Delta(1-\Delta)}{(P_1 - P_2)^2}$$

Where,

Z_α= standard normal deviate corresponding to 95% confidence level set at 1.96

Z_β = Standard normal deviate to a power of 80% set at 0.84

P_1= Proportion of exposed (experimental group) - assumed 0.50

P_2= Proportion of unexposed (control group) determined by $P_2 = \frac{P_1 X\ OR}{P_1(OR-1)+1}$ = 0.66

$\Delta = average\ proportion \frac{P_1+P_2}{2}$ = 0.58

$1 - \Delta = 1 - 0.58 = 0.42$

$$n = \frac{2(1.96 + 0.84)^2 (0.58)(1-0.58)}{(0.50 - 0.66)^2}$$

$$n = 150$$

Therefore, a total of n=150 participants was required to be recruited into the study.

Initially, the cross-sectional study was started at the National Hospital Abuja (n=124), followed by UCH, Ibadan (n=100). The original plan was to carry out the cross-sectional study only at NHA, however as a result of logistical and funding challenges, the study was moved to a hospital close to student's home in Ibadan, to manage research costs. Data was collected by convenience sampling method. In total, questionnaires were effectively completed by 224 participants (214 women and 10 men) at NHA and UCH. Men and women aged between 21 and 45 years attending the infertility

outpatient clinics, and other gynaecological and andrology clinics for infertility treatment were recruited.

At the outset, men were included in the research plan because evidence shows that male infertility is a major contributor to infertility in couples (Evers, 2002; Turchi, 2015; Pescatori, 2015). Evidence also suggest that although men and women may cope differently to the psychological distress associated with infertility, both genders suffer psychosocial pressures because of delayed childbearing (Lee et al, 2001; Inhorn & van Balen, 2002, Alosaimi et al, 2016). A study by Alosaimi et al (2016), suggested that infertility-related psychosocial pressures were prevalent in 39% males and 48% of female seeking treatment for infertility. In order to gain an all-inclusive insight into the prevalence of infertility related distress, men had to be included.

Permission to carry out the study was given by the ethical and research committee of both NHA and UCH (NHA/EC/035/2014 and UI/EC/17/0061, respectively) as well as the University of Liverpool (Reference no: 2121).

Questionnaire Design

The survey questionnaire is divided into 4 main sections in the following order:

a. Demographic data of patients participating in research.
b. Data on infertility treatment and stage of infertility treatment.
c. Data on spousal and family relationships.
d. Data on psychological health and wellbeing of patients (12 item General Health Questionnaire- GHQ12).

The questionnaire was pre-tested to determine the effectiveness of the questionnaire in collecting required data corresponding to the research objectives and research questions among the target population (Backstrom & Hursch, 1963; Churchill 1979; Hunt et al, 1982). The outcome of pretesting show the questionnaire to be effective in collecting the required data for the research population and settings. It was also discovered that the questionnaire was too long for the participants too long for the participants to fill within the busy clinical setting. The questionnaires were thus amended to accommodate the time limitations, without depleting the strength of data.

Data Analysis

Data was analysed using a multi-level analytical approach to examine the relationships between outcomes (psychological morbidity), and individual and group level determinant variables. The 'no responses' data were also included in analysis to determine if behaviour produced a trend in the prevalence of psychological morbidities amongst infertility patients. This multilevel approach overcomes common methodological barriers associated with conventional regression analysis in epidemiology, where correlation among individuals sharing the same local environment is not accounted for. It allows for the examination of variability in outcomes between individuals as well as between higher level units. The Chi squared statistic and Fisher's exact test were used in testing for association between categorical variables. Furthermore, the strength of association was determined using Phi and Cramer's V correlation analysis. The purpose was to determine strengths of association after chi-square has determined significance of association. All analyses were done using the Statistical Package for Social Sciences 10.0 for Windows (SPSS Inc. Chicago, Ill.). A value of $p<0.05$ was considered significant.

Data collected from the two hospital were first analysed separately as two datasets, followed by analysis as a combined data set. The presence of infertility and psychological morbidity was examined both on the crude level, and stratified by age, level of education, marital and relationship status, stage of infertility treatment as well as duration of infertility. Factors such as age, sex, and marital status, medical history of infertility treatment and family history of domestic violence were examined. Uncompleted question items denoted as 'no response' at each level were included in analysis for the parameter being measured, adding up to a count (N) of 224 on each demographic or clinical characteristic (Table 3.2).

The data from the two sites were combined and analysed. They were tested for statistical significance as appropriate, using the Pearson's Chi squared test, Chi squared test for trend using the Mantel-Hanzel method for ordered categories, or Fischer's exact test. The strength of association between various patient characteristics and the presence of psychological caseness was

also conducted using the Crammer V correlation for all except for gender, where the Phi Correlation coefficient calculations were used to determine strength of association.

Ethical Considerations:

Confidentiality of Data

Strict confidentiality was upheld at all stages of this study. All personal and identifiable data was stored away in a locked place or in a password protected computer. Although patients' names and contact details (telephone number) were required on the cover page of the survey questionnaire, these documents were stored and locked away at all times. This personal data was required for follow-up for those who would be eligible for the pilot RCT (Chapter 4). Questionnaires were self-reported, with the support of the research assistant, if required for clarifications. Participants were advised that the findings of the research will be published and publicly accessible to all. However, all reported data and results were non-identifiable.

Translation of protocol to local language

The informed consent forms and the participant information sheets were translated into the local language for patients who are not literate in the use of the English language. Also, a translator was readily available to patients during the research process, especially during collection of data for the cross-sectional survey, which were all in English.

Beneficence to patients

Patients were advised their participation in the research would contribute to research that seeks to provide total care for infertility patients especially within the African context. Patients were also advised that this would contribute to evidence base and information on how to provide better care for infertility patients that would be in accordance with the experiences of infertility patients within our community and the society at large.

Non-Maleficence to Patients

Questionnaires were handed out to patients privately and sensitively. Some patients experienced emotional discomfort while filling in the

questionnaires related to their recollection of experiences. This was dealt with by confidentially signposting patients to local support organisations affiliated with NHA and UCH as appropriate.

Voluntariness

Patients were also advised of their right to withdrawal at any stage of the research, without consequences and without affecting their statutory right while receiving treatment at NHA, UCH, and/or access to treatment elsewhere in the future.

Results:

The recruitment took place over a period of 2 years. Recruitment started at NHA from September 2015 to December 2016 (n=124); followed by UCH (n=100) from March 2017 to March 2018. Altogether two hundred and twenty-four patients consisting of 214 women and 10 men, were recruited into the study from the two hospitals.

According to self-report, participants were mainly women (96%) aged over 35 years (46%), who were married (89%) with no pre-existing children (69%), (table 3.3). Most respondents reported themselves of having a higher level of education (82%), and in employment (83%). The majority recounted no previous history of domestic violence (60%), and no previous history of marital breakdown as a result of infertility (89%). The most common type of infertility was secondary infertility (45%), and participants had been seeking treatment for infertility for at least 2 years, and were at the initial referral stage for treatment. Most participants had a GHQ 12 score indicative of no "psychological caseness" (56%). When asked about a previous history of spontaneous or induced abortion in the past, the majority reported no previous history of spontaneous or induced abortion (54% and 50%, respectively).

Of the 224 participants recruited at NHA and UCH, 29% (n=65) classified themselves as having primary infertility, 45% (n=101) as secondary infertility, 4% (n=9) as male infertility, and 17% reported their classification as

unknown (n= 37). The data for duration of infertility were collected in categories. The group with the highest frequency of 50% (n=113) were those who had been attending for a minimum of 2 years, followed by 26% of participants, who had been attending for over 5 years (n=58). Only 16% (n=36) of participants reported to have been attending for infertility treatments for 3-5 years. Although the majority of the participants reported no history of domestic violence, a large proportion (35%; n=79) reported experiencing domestic violence currently (30%; n=68), or experiencing it within the last 6 months (5%; n=11). Only approximately 5% (n=12) of participants reported a marital or spousal relationship breakdown as a result of infertility problems. The prevalence of a reported history of induced abortion amongst the female participants was 42% (n=93), whilst a history of spontaneous abortion was reported in 37% of the women (n=83). Although a large majority of participants have no children (69%, n=154), a significant proportion of participants stated that they had up to 5 pre-existing children. Thirty-six (16%) participants had 1 child, 17 (8%) participants reported to having 2-4 children, and 9 (4%) participants stated that they had more than 5 children.

The parameters measured by the survey questionnaire were described and analysed individually (Table 3.3). There were no significant differences in the trend of the socio-economic and demographic parameters of participants recruited from NHA and UCH, when compared.

Table 3.3: Socio- demographic and some clinical characteristics of the recruited participants at NHA and UCH, Nigeria.

Characteristics (N= 224)		NHA (%)	UCH (%)	Total (%)
Participant gender				
Female		120 (96.8%)	94 (94.0%)	214 (95.5%)
Male		4 (3.2%)	6 (6.0%)	10 (4.5%)
Age group in years				
25 years or less		5 (4.0%)	2 (2.0%)	7 (3.1%)
26-30		21 (16.9%)	26 (26.3%)	47 (21.0%)
31-35		36 (29.0%)	31 (31.3%)	67 (30.0%)
>35 years		62 (50.0)	40 (40.4%)	102 (45.5%)
No response		0 (0.0%)	1 (0.01%)	1 (0.4%)
Marital status according to participants				
Unmarried		6 (4.8%)	11 (11.0%)	17 (7.6%)
Married		113 (91.1%)	84 (84.0%)	197 (88.0%)
Separated/ Divorced		5 (4.0%)	2 (2.0%)	7 (3.1%)
No response		0 (0.0%)	3 (3.0%)	3 (1.3%)
No of pre-existing Children				
0		86 (69.9%)	68 (68.0%)	154 (68.7%)
1		22 (17.9%)	14 (14.0%)	36 (16.0%)
2-4		10 (8.1%)	7 (7.0%)	17 (7.6%)
5 or more		5 (4.1%)	4 (4.0%)	9 (4.1%)
No response		1 (0.8%)	7 (7.0%)	8 (3.6%)
Level of Education				
Primary		2 (1.6%)	1 (1.0%)	3 (1.3%)
Secondary		17 (13.7%)	17 (17.0%)	34 (15.2%)
Higher Education		105 (84.7%)	79 (79.0%)	184 (82.1%)
No response		0 (0.0%)	3 (3.0%)	3 (2.4%)
Employment Status (n=214)				
Unemployed		20 (16.1%)	8 (8.0%)	28 (12.5%)
Self-employed		29 (23.4%)	40 (40.0%)	69 (30.8%)
Employed		70 (56.5%)	47 (47.0%)	117 (52.2%)
No response		5 (4.0%)	5 (5.0%)	10 (4.5%)
Infertility Type				
Male factor		5 (4.0%)	4 (4.0%)	9 (4.0%)
Female Factor	Primary	38 (30.7%)	27 (27.0%)	65 (29.0%)
	Secondary	58 (46.8%)	43 (43.0%)	101 (45.1%)
Unknown		18 (14.5%)	19 (19.0%)	37 (16.5%)
No response		5 (4.0%)	7 (7.0%)	12 (5.4%)
Duration of Treatment				
2 years		56 (45.2%)	57 (57.0%)	113 (50.4%)
3-5 years		23 (18.5%)	13 (13.0%)	36 (16.1%)
>5 years		39 (31.5%)	19 (19.0%)	58 (25.9%)
No response		6 (4.8%)	11 (11.0%)	17 (7.6%)
History of spontaneous abortion				
None		66 (53.2%)	55 (55.0%)	121 (54.0%)
1		16 (13.0%)	17 (17.0%)	33 (14.7%)
2		15 (12.1%)	6 (6.0%)	21 (9.4%)

3 or more	21 (16.9%)	8 (8.0%)	29 (13.0%)
No response	6 (4.8%)	14 (14.0)	20 (8.9%)
History of Induced abortion			
None	57 (46.0%)	55 (55.0%)	112 (50.0%)
1	22 (17.7%)	16 (16.8%)	38 (17.0%)
2	16 (12.9%)	7 (7.0%)	23 (10.3%)
3 or more	20 (16.1%)	12 (12.0%)	32 (14.3%)
No response	9 (7.3%)	10 (10.0%)	19 (8.4%)
Stage of Infertility Treatment			
Initial Referral to fertility specialist	45 (36.3%)	32 (32.0%)	77 (34.4%)
Diagnostic tests and procedures	32 (25.8%)	21 (21.0%)	53 (23.7%)
Definitive Diagnosis, awaiting treatment	18 (14.5%)	14 (14.0%)	32 (14.3%)
1 or more completed cycles of treatment	15 (12.1%)	14 (14.0%)	29 (12.9%)
Treatment stopped	4 (3.2%)	4 (4.0%)	8 (3.6%)
No response	10 (8.1%)	15 (15.0%)	25 (11.1%)
History of Domestic Violence due to Infertility			
Never	70 (56.5%)	64 (64.0%)	134 (59.8%)
Yes, Currently	43 (34.7%)	24 (24.0%)	69 (30.8%)
Yes, in previous relationship(s)	6 (4.8%)	5 (5.0%)	11 (4.9%)
No response	5 (4.0%)	5 (5.0%)	10 (4.5%)
History of infertility induced divorce or relationship breakdown			
None	111(93.3%)	89 (89.0%)	200(89.3%)
1	6 (5.0%)	2 (2.0%)	8 (3.6%)
2	0 (0.0%)	2 (2.0%)	2 (0.9%)
3 or more	2 (1.7%)	0 (0.0%)	2 (0.9%)
No response	5 (4.0%)	7 (7.0%)	12 (5.3%)
Presence of Psychological Morbidities (GHQ12 Score ≥3			
No psychological distress	67 (54.0%)	59 (59.0%)	126 (56.2%)
Psychological distress	57(46.0%)	39 (39.0%)	96 (42.9%)
Incomplete GHQ 12	0(0.0%)	2 (2.0%)	2 (0.9%)

Psychological Morbidity

During data collection, 222 out of 224 participants completed the GHQ12 section of the questionnaire. Data from two participants who did not complete analysis were excluded from this section of data analysis. The mean GHQ12 score was 2.97 (SD=3.066). Of those who were included, 96 participants (43.2%) were recorded to have a GHQ 12 score of 3 or more (mean score= 5.81; SD=2.53). The majority of the participants recorded a GHQ12

score from 0 to 2 (56%; Fig 4.1). The most frequent GHQ12 score was 0 (n=61; 28%), while the least frequent GHQ12 score was 11 (n=1; 0.5%).

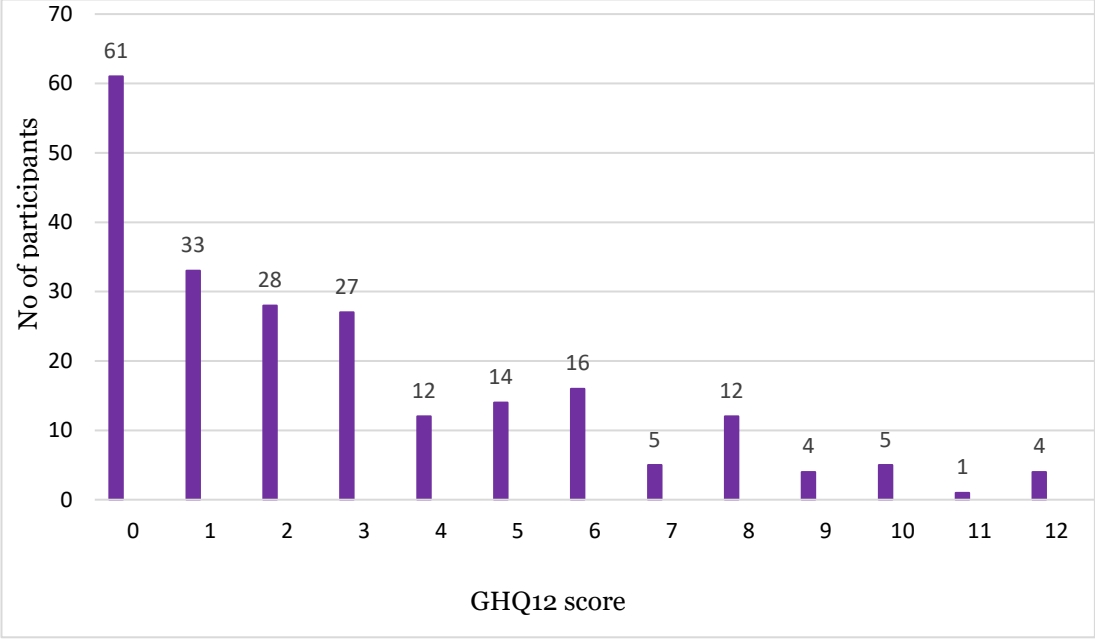


Fig 3.1: Graph showing number of participants by GHQ 12 scores among patients attending NHA and UCH for infertility treatments.

Predictors of psychological morbidity.

Table 3.4 summarizes the association between psychological morbidity outcome measures and the characteristics of the infertility subjects. Those aged over 35 years old had the highest prevalence of psychological morbidity; the age group, employment, infertility type, and a history of induced abortion and/or miscarriage were not statistically significantly associated with the GHQ12 measured. The statistically significant associations are marital status, level of education, history of pre-existing children, duration of treatment, and a current or previous history of domestic violence (Table 3.4).

Table 3.4: Association between psychological morbidity and the demographic and clinical characteristics of the infertility patients at NHA and UCH, Nigeria.

Characteristic	Categories	GHQ12 Scoring		Total	P - value	Corr. Co-eff.
		0-2	≥3			
Sex	Female	117	95	212	0.03	0.1
	Male	9	1	10		
Total		126	96	222		
Age (years)	25 or less	4	3	7	0.3	0.2
	26-30	29	18	47		
	31-35	41	24	65		
	>35	51	51	102		
	No response	1	0	2		
Total		126	96	222		
Marital Status	Married	116	80	196	<0.001	0.4
	Sep./Divorced	4	3	7		
	Unmarried	4	13	17		
	No response	2	0	2		
Total		126	96	222		
Children	0	87	67	154	0.004	0.2
	1	22	14	36		
	2-4	9	8	17		
	≥5	5	4	9		
	No response	3	3	6		
Total		126	96	222		
Level of Education	Primary	2	1	3	<0.001	0.3
	Secondary	19	14	33		
	Higher	104	80	184		
	No response	1	1	2		
Total		126	96	222		
Employment	Unemployed	19	9	28	0.6	0.1
	Employed	64	51	115		
	Self-employed	39	30	69		
	No response	4	6	10		
Total		126	96	222		
Infertility Type	Male primary	8	1	9	0.2	0.2
	Male secondary	1	0	1		
	Female primary	44	21	65		
	Female secondary	50	50	100		
	Unknown	18	19	37		
	No response	5	5	10		
Total		126	96	222		
Duration of Treatment	2 years	70	43	113	0.03	0.2
	3-5 years	26	10	36		

	>5 years	21	37	58		
	No response	9	6	15		
Total		126	96	222		
History of Abortion	0	66	46	112	0.6	0.2
	1	18	20	38		
	2	10	13	23		
	≥3	20	12	32		
	No response	3	5	8		
	Males (N/A)	9	0	9		
Total		126	96	222		
History of Miscarriage	0	74	47	121	0.2	0.2
	1	17	16	33		
	2	9	12	21		
	≥3	14	15	29		
	No response	3	5	8		
	Males (N/A)	9	1	10		
Total		126	96	222		
History of DV due to Infertility	Never	91	42	133	<0.001	0.3
	Previously	7	4	11		
	Current	21	47	68		
		7	3	10		
Total		126	96	222		

Figures 3.2 to 3.9 graphically shows the trend of the different variables measures against the presence or absence of psychological caseness. On the x-axis, the labels are represented as Nil, 0, and 1. The '0' and '1' is indicative of 'no psychological caseness' and 'psychological caseness', respectively. 'Nil' represents those participants (n=2), who had not completed the GHQ12 section of the questionnaire. These two participants were included in the graphical representation to show the demographic trend of the participants who were unable to successfully complete their questionnaires, and to assess if there are peculiarities within this specific group.

Out of the 96 who were psychologically distressed according to the GHQ12 score, psychological morbidity was predominantly higher in females ($X2= 4.715$; df=1; p value= 0.03; r=0.1). There were 95 females (44.8% of all females) and 1 male (10 % of all males) who were identified to have a psychological morbidity according to the GHQ 12 scoring method (Fig 3.2).

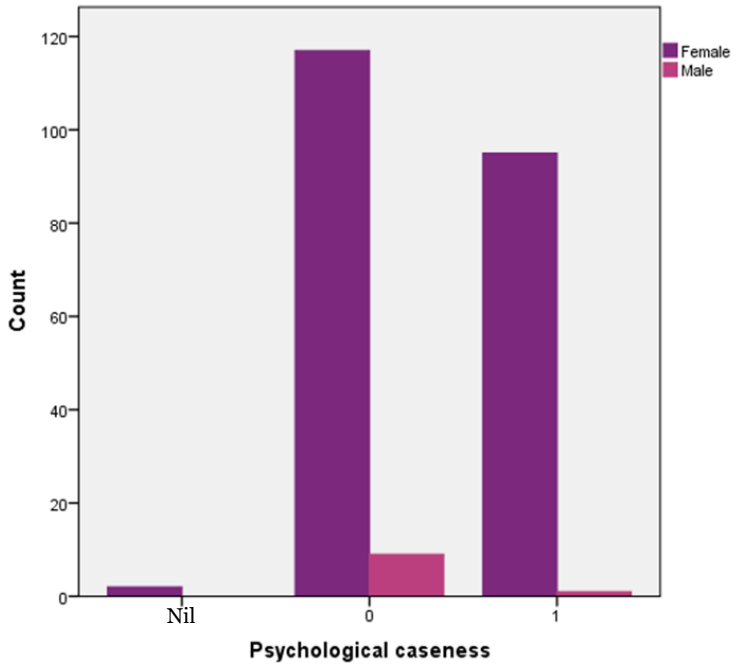


Fig 3.2: Number of patients by gender with a GHQ12 indicative of psychological distress (p value= 0.03, Chi squared)

When considering age, the highest prevalence of psychological distress was reported in those aged above 35 years of age (Fig 3.3), with half of participants indicating psychological distress according to the GHQ12 scoring. Approximately 40% of the other age groups were found to have a GHQ 12 score of ≥3; which is indicative of the presence of psychological morbidity. However, significance testing indicates that this result probably occurred by chance, with a correlation coefficient of 0.3 (X^2=6.921; df=8; p value=0.3; r= 0.3). The graph shows similarities in trend of sex distribution irrespective of a presence or absence psychological caseness (0; 1). The "Nil" column denotes the participants who did not complete the GHQ12 questionnaire.

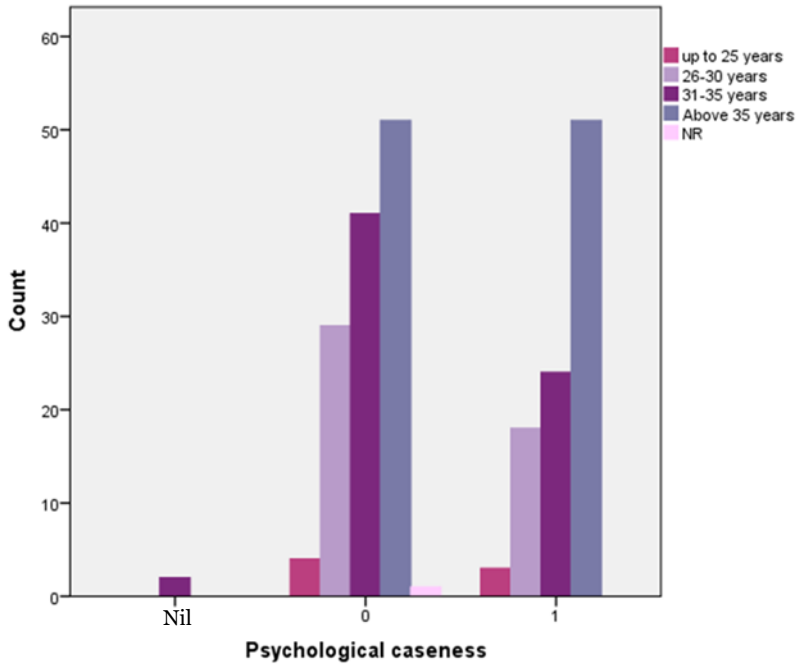


Fig 3.3: Number of patients by age with a GHQ12 indicative of psychological distress (p value= 0.3, Mantel-Hanzel method).

Psychological morbidity was also measured according to the cause of infertility (Fig 3.4a). Patients were categorised into 4; the named categories of infertility were classified as male, primary, secondary, and unknown causes. Another analysis was also done classifying the infertility factor such as male, female or unknown factor. The results showed no significant differences in analysis outcomes. The trend of the types or cause of infertility was similar in irrespective of presence of psychological caseness (Fig 3.4). The highest prevalence of psychological distress was observed in the group an unknown cause of infertility (51.4%), followed by with female factor, secondary infertility (49.5%; 43.0%), primary infertility (32.3%), and male infertility (11.1%). The prevalence in those with male infertility was significantly lower than for the other causes (X^2= 10.569; df=8, p value= 0.2; r=0.2).

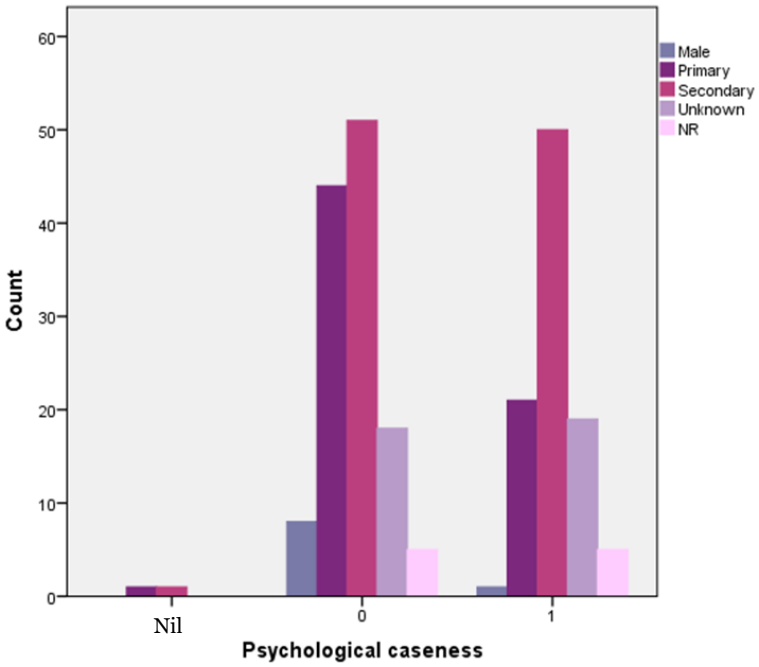


Fig 3.4: Number of patients by infertility type with a GHQ12 indicative of psychological distress (p value= 0.02, Chi squared).

Results also showed that the duration of infertility treatment was associated with the prevalence of psychological distress among infertility patients (X2= 15.633; df=6; p value=0.03; r=0.2). The highest proportion of psychological morbidity was identified in patients with the longest duration of infertility- more than 5 years (63.8%). This was followed by those with a duration of 2 years (38.1%), and patients who had been attending for treatments for 3 to 5 years (27.8%), respectively (Fig 3.5).

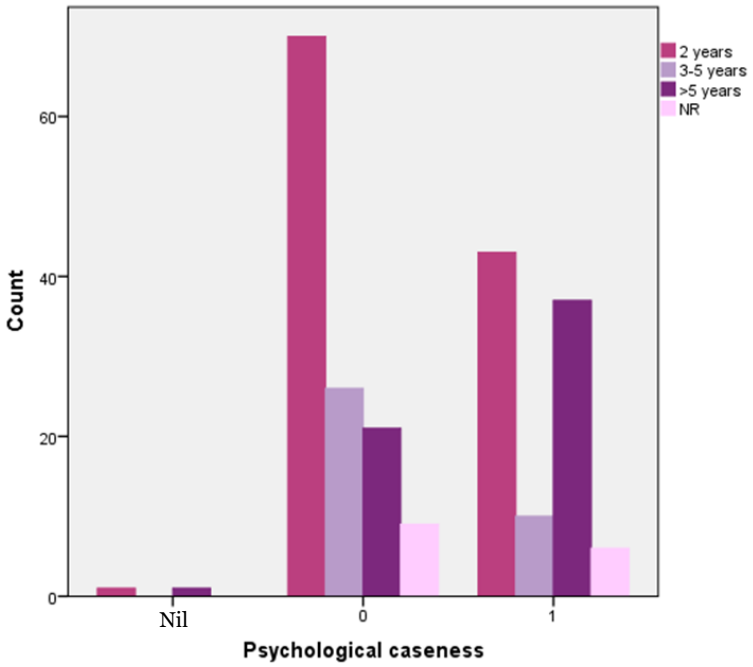


Fig 3.5: Number of patients by duration of infertility treatment with a GHQ12 indicative of psychological distress (p value= 0.03, Mantel-Hanzel method).

Among patients with a history of domestic violence, patients were categorised into 3 - those who had no history of domestic violence, those who had a previous history and those who were currently experiencing domestic violence as a result of infertility (Fig 3.6). Of the three, the category with the largest proportion of patients with psychological distress was observed amongst patients who identified as currently undergoing domestic violence at 69.1%. Analysis showed an ascending trend of psychological distress according to the degree of current exposure to domestic violence (X^2 = 27.226; df=6; p value <0.001; r= 0.3).

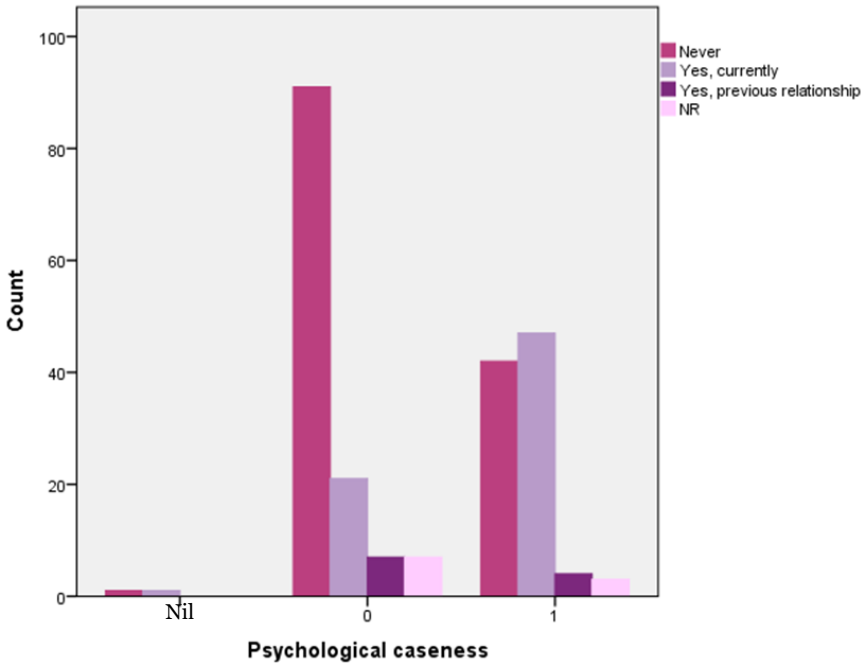


Fig 3.6: Number of patients by exposure to domestic violence due to infertility, with a GHQ12 indicative of psychological distress (p value= <0.001, Mantel-Hanzel method).

Remarkably, the analysis of marital status showed that 76.4% of patients who identified as unmarried presented with a GHQ12 score indicative of a psychological distress (Fig 3.7). Approximately 40% of patients who identified as married, as well as those who indicated that they were divorced or separated, had GHQ12 levels indicative of an underlying psychological morbidity (X^2=45.439; df=6; p value= <0.001; r=0.4).

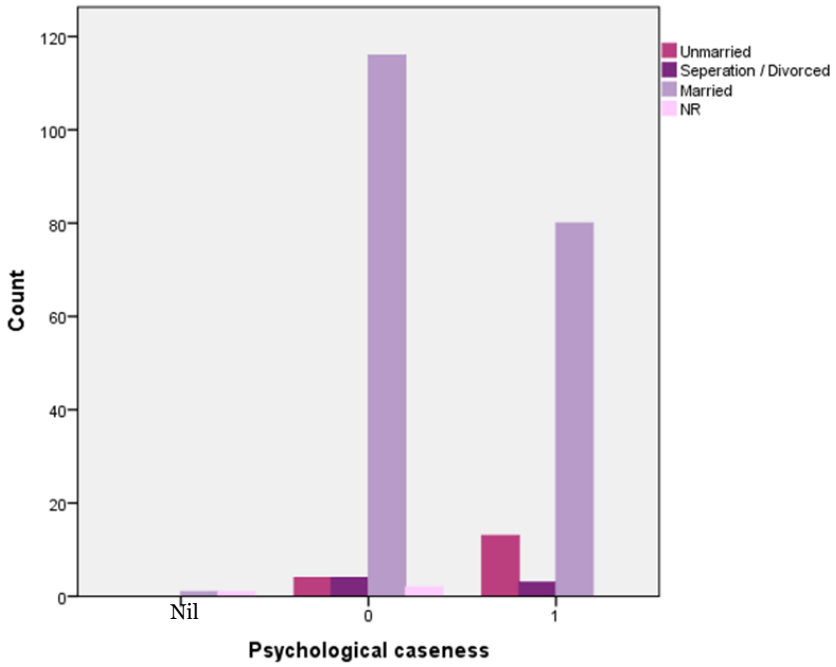


Fig 3.7: Number of patients by marital status, with a GHQ12 indicative of psychological distress (p value= <0.001, Chi squared).

Results also showed that psychological distress amongst infertility patients was present irrespective of having pre-existing children in the same trend as those who had no psychological distress (X^2= 22.267; df=8; p value= 0.004; r=0.2). Psychological caseness was also present irrespective of level of education in the same trend as those who had no distress. (X^2= 39.135; df=6; p value= <001; r=0.3). These trends are represented in Fig 3.8 and 3.9 respectively.

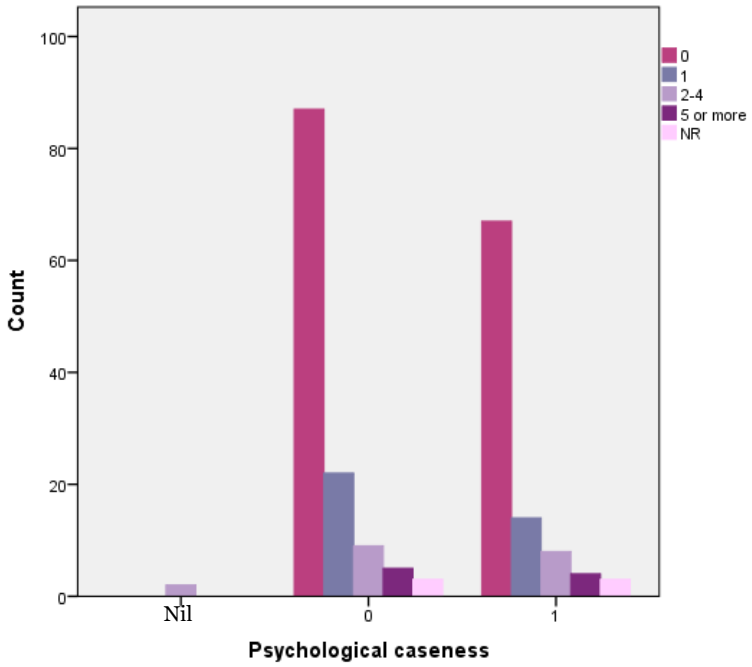


Fig 3.8: Number of patients by history of pre-existing children with GHQ12 score indicative of psychological distress (p value=0.004; Chi squared)

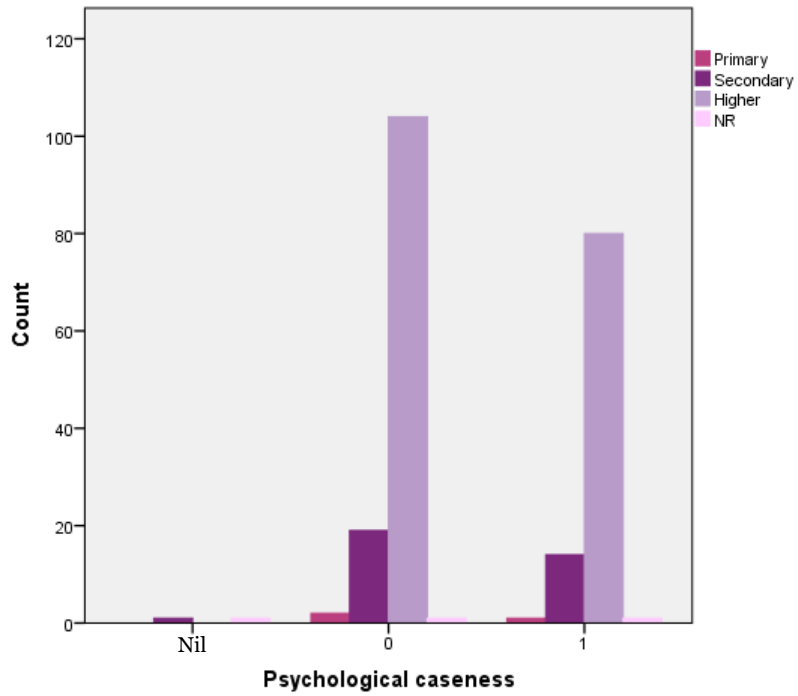


Fig 3.9: Number of patients by level of education with GHQ12 score indicative of psychological distress (p value=<0.001; Chi squared)

Strength of association of variables:

The analysis of the strength of association (denoted as "r"), between the different variables and the presence of psychological caseness amongst infertility patients showed weak positive correlation. The minimum r value was 0.1 in gender, infertility type/factor, and employment status, while the strongest correlation of r=0.4 was recorded in marital status. Table 3.5 shows the strength of association (r value) between presence of psychological caseness and the varying participant characteristics and the statistical significance the association of each variable (p value).

Table 3.5: Table showing correlation co-efficient between variables using Phi and Crammer V correlation analysis.

Participant characteristic	r value	p value
Gender	0.1	0.09
Age group	0.2	0.4
Marital status	0.4	<0.001
Level of education	0.3	<0.001
History of pre-existing children	0.2	0.004
Employment status	0.1	0.6
Infertility type	0.2	0.2
Infertility factor	0.1	0.6
Duration of treatment	0.2	0.01
History of spontaneous abortion	0.2	0.2
History of induced abortion	0.3	0.1
History of domestic violence	0.3	<0.001

Compared to the other variables listed in the table 3.5, correlation was stronger in marital status, level of education and history of domestic violence with strong statistical significance of < 0.001. The other variable showed weak correlation with no statistical significance. This result suggests that as one variable increase or decreases, there is a lower likelihood of there being a relationship with the occurrence infertility-related psychological distress, described in this study as psychological caseness.

Discussion:

In this cross-sectional study, psychological distress was recorded in 43.2% of patients who were attending the clinics for infertility treatment. The predictors of psychological distress were being female, being unmarried, infertility type, the duration of treatment, and a positive history of domestic abuse.

Previous studies from Africa and the middle-east, including Nigeria, have reported a prevalence ranging from 39.5% to 53.8% (Dyer et al, 2005; Ukpong & Orji, 2006; Al-Homaidan, 2011; Coker et al, 2013; Ikeako et al, 2015; Oladeji & OlaOlorun, 2018). This shows a persistent high prevalence of infertility related stress amongst patients across different populations over the last decade. Prior studies in Nigeria have focused on the psychological impact of infertility among women. However, this study set out to determine the prevalence of infertility related psychological distress among both men and women as the infertility profile shows that men and women contribute equally to the prevalence of infertility in Nigeria (Mascarenhas et al, 2012). Furthermore, men also want to have biological children and could experience psychological trauma as a result of their inability to cause conception in a female partner.

In this study, there was a disproportionately higher attendance and response by women attending for infertility treatment (96%), than their male counterparts (n=214 women, n=10 men). The small sample means that the results for psychological distress amongst male patients may not be represented in this group. This can be attributed to the disparities in the investigative and treatment plans between men and women with infertility. The men attend their seminal fluid analysis appointment very discreetly, early in the morning, and leave immediately after, not wishing to draw any attention to themselves. However, the women do not have the option to attend unnoticeably, as they have to be present at scheduled clinic time, which usually begins at midday. The disparities in choice between men and women with regards to access to infertility treatment reinforces the stigmatising perception that infertility is 'visibly' a woman's problem. It also means that most male attendees were not included in our sample that was generally selected later in the day.

The association between being female and infertility related psychological distress could be further explained by the disproportionately higher stigma and socio-economic consequences that women suffer as a result of infertility in African populations and indeed in Nigeria. There is a heightened sense of urgency to conceive by women due to societal expectations, often complicated by the limited time that comes with age and the "reproductive window of opportunity". Thus, it is understandable that half of patients with age greater than 35 years displayed psychological distress according to the GHQ12 scoring. In addition, the male participants included in this sample were attending with their spouses. These are men therefore, who are likely to be supportive spouses with a potentially more holistic view of infertility management. This assumption is supported by prevalence of psychological morbidity among the men within this group; only 1 out of the 10 men was identified as having psychological distress according to GHQ12 scoring, compared to 45% of women.

Marital status was also a contributing factor to the prevalence of infertility related psychological distress with 76% of unmarried participants having psychological distress according to the GHQ12 scoring. This phenomenon could be explained by an underlying social construct that appears to increase the anxiety or distress levels of patients who were unmarried but also actively seeking to become pregnant as evidenced by their attendance for infertility treatments. In many Nigerian cultures, the formal wedding ceremony is usually preceded by traditional betrothal or engagement ceremonies whereby the couple in question are seen as married by all, and in all, but on paper. It is common practice that conception by the couple is envisaged and promoted before marriage to ensure that the woman can 'give' the much-desired children to continue in the family lineage.

Psychological distress was equally distributed across all groups irrespective of pre-existing children. Prevalence ranged from 40-50. This outcome suggests that when there is a strong desire for conception, the inability to conceive creates a longing or sense of loss that can lead to psychological morbidities. There are many reasons why people may wish for a desired child(ren); it could be the desire for a specific gender, or the desire for

a child in a new relationship or marriage. Oladeji et al (2018) suggest that there is a longing for more children especially among couples with female only children who want at least one male child (Oladeji & OlaOlorun, 2018).

This study suggests that the type of infertility was also a predisposing factor for infertility related stress. Approximately half of those with secondary infertility and infertility due to unknown causes had a positive psychological caseness according to the GHQ12 scoring (49.5% and 51.3% respectively; p value= 0.02). Psychological morbidity was much lower in patients with primary infertility and male infertility (32.8% and 11%, respectively). This differed from previous studies which seemed to suggest that stress and depression were significantly higher in women with primary infertility when compared to women with secondary infertility (Alhassan et al, 2014; Ikeako et al. 2015). There are relationships between having been previously pregnant and having infertility related psychological distress. Psychological distress could come from a sense of guilt or grief, guilt after the loss of a previous pregnancy through induced abortion of an unwanted pregnancy, or grief as a result of a spontaneous abortion (miscarriage) of a desired foetus. A history of the inability to successfully carry a pregnancy to term justifiably leads to a double source of anxiety. There is the initial anxiety of having a successful conception when trying to have a desired child, followed by the anxiety of being able to successfully carry the pregnancy to full term to deliver a healthy live baby. Also, for patients who have infertility as a result of unknown causes, the anxiety of not knowing the reason why they are unable to successfully conceive is a justifiable factor contributing to infertility related psychological distress.

Regarding infertility treatment, this study suggests that longer duration of infertility treatment was also a predisposing factor to psychological morbidities. It corresponds to a study by Patel et al (2016), who found that the likelihood of infertility-specific stress experienced by women is higher when they experience more than 5 years of married life and in those with over 5 years of infertility duration. The delay in conception, worsened by the experience of unsuccessful treatments, has a profoundly negative effect on family life, if left unmanaged. Evidence shows that subfertility and/or infertility is associated with intimate partner violence (IPV) in low- and middle-income countries

(Carmen et al, 2016). Infertility leads to relationship problems, marital discord and in extreme cases domestic violence as seen in the findings of this research. The rate of 40% is also in keeping with previous study by Ameh et al (2006), where 41.6% of the women in three different infertility clinics in Nigeria, had suffered domestic violence due to their infertility. Another study by Ardabily et al (2010), in Iran, found a much higher prevalence of domestic violence as a result of infertility (61.8%). Irrespective of the predominance of domestic violence, it is understandable that majority of those who had been exposed to domestic violence in this study had their GHQ12 indicative of psychological distress (64.6%). The domestic violence is related to stress at home and in the relationship, which is increased by infertility.

Our main challenge of doing the study was the role of bias in the self-reported questionnaires by the participants. Bias can be defined as any systematic error in the design, conduct, or analysis of a study (Althubaiti, 2016). Self-report bias in terms of recall bias and social desirability bias were those identified to have been a challenge in relation to this study.

During this study, participant responses depended on their ability to recall past events, thereby indicating potential recall bias. In many African communities, infertility exposes people to unpleasant experiences clinically, culturally and socially. In the survey questionnaire, participants were asked about sensitive topics such as marital history, history of previous abortion and miscarriages, history of domestic violence and so on. Studies show that underreporting of poor mental health is a major problem for identifying and treating mental health problems in clinical practice (Hunt et al, 2003). For some patients, forgetting about those unpalatable events is a coping mechanism. Thus, the researcher has to rely on the participants' willingness to share such information.

The accuracy of participant responses could also be influenced by social contexts and social desirability. Participants could be motivated to give responses that are socially acceptable, thereby avoiding shame and humiliation. The motivation is to conform to socially acceptable morals and expectations. This leads to the exaggerating of behaviours seen as socially acceptable, and underreporting of behaviours that are perceived as improper

(Schroder et al, 2003; Althubaiti, 2016). However, this bias was minimised by assuring participants of the strict confidentially of the information being shared.

Further to the issue of the accuracy of participant responses, there were significant levels of 'no responses' to certain questions when participants were filling out their questionnaires. There were 'no responses' recorded in all but one parameter which was gender of participants. The 'no response' rate ranged from 0.4% in 'participant age group', up to 11% in 'stage of infertility treatment'. Two participants also did not complete the GHQ12 section of their questionnaire. The findings of the study showed no distinctiveness amongst these two patients that could have predisposed to their inability to complete the questionnaire. There are however some hypotheses drawn from this finding which could be firstly, data was collected during busy clinic sessions where participants were waiting to be seen and/or waiting to be called for further tests that would limit the time they had to fill in questionnaires. Another hypothesis is that participants may have not responded to certain questions to avoid exposure to the 'real answers' to 'difficult' questions. This could have been developed as a coping mechanism to manage their psychological wellbeing or perceptions. Although the findings of the study showed no differences in presence or absence of psychological caseness among the 'no response groups, further research will be required to explore these hypotheses.

Another source of bias is the prevalence of male infertility in this study which was found to be significantly lower than the evidence from previous studies. The prevalence of male infertility in Nigeria accounts for 20 - 40% of infertility cases (Panti & Sununu 2014, Ikechebelu et al, 2003). Male factor infertility in this study was found in 4% of participants. The findings were based upon patient response in group of predominantly women, which could have contributed to the large discrepancy between findings of this study, compared with the prevalence of male infertility from previous scientific literature evidence. During planning of further research, strategies that increase male involvement and recruitment should be incorporated by better

planned engagement of laboratory service providers, andrology clinics to include men who attend for seminal fluid analysis.

Data for this cross-sectional survey was collected during general infertility clinic sessions which was a very busy setting. Research is a time-consuming activity that requires planning, management and negotiation between the researcher, the participants, as well as the health professionals working within the busy clinical setting (Haller, 1986). The questionnaires were pre-tested to ensure that the length was acceptable for the limited time available. Also, the doctors, nurses and administrative staff were informed of the research protocol, ensuring that all were aware of the research activities at the infertility clinic. This created a team working environment, which reduced some of the pressure of time constraints. Nevertheless, considerations for different methodological approaches to data collection such a retrospective cohort study of clinical records, in addition to self-reported questionnaires, could provide more robust source of data, producing stronger associations and correlation coefficients, thereby improving upon the validity of results.

Even so, the findings of this study show how infertility as not only a clinical problem for those affected, but also has economic, social and cultural implications for the patients. The results show the prevalence of infertility related psychological distress, irrespective of age, social class or having pre-existing children. This suggests that the quest of a desired pregnancy not only existed due to childlessness, but also as a need to fulfil a socio-cultural obligation in marriage (or an intended union), in the community, and/or to have a desired gender (usually a male child to carry on a family legacy). This reinforces the need to sensitise health workers, most especially infertility specialists, to the psychological burden of infertility that their patients could be struggling to cope with, rather than just the biomedical treatments. Infertility specialists and other health workers should become more cognisant to how they relate with their patients and to develop skills that enable them recognise the red flag signs of psychological distress or poor mental health in their patients.

Another recommendation is the development of effective interventions to manage infertility induced psychological distress. Infertility has multiple

effects- physical, psychological, and social- and any approach to management should therefore be multi-disciplinary. Infertility support groups involving a multi-disciplinary group of health workers, patients, and members of the community could be created to tackle the social effects of infertility through health promotion and health education activities. This has the potential to confront and challenge infertility-related stigma and injustice within the communities.

Finally, there is the need for commitment by the government and political stakeholders towards enforcing a zero-tolerance to domestic violence. Specific laws need to be put in place that punish those causing intimate partner violence or domestic violence by members of the family. In addition, there is the need for awareness programmes that disseminate information about the stipulated laws and their enforcement agencies. This could empower victims to exercise their rights, by rejecting and fighting against abuse and victimisation.

Conclusion

In conclusion, the psychological morbidities associated with infertility in Nigeria is a long-standing problem that remains relevant, even in current times. This study has identified predisposing factors to the development of psychological distress. They include being female, marital status, infertility type, long standing duration of treatment, and the exposure to domestic abuse. There is a significant need for the development of interventions to manage the identified psychological distress as well as putting policies in place to protect victims of infertility-related psychological distress and domestic violence.

Chapter 4:
The Development of FELICIA: An Intervention for the management of Psychological distress associated with infertility.

Introduction

Infertility is defined as failure to conceive after regular unprotected sexual intercourse for 1 year (Zegers-Hochschild et al, 2009). The WHO in 1992 estimated that 8 to 12% of couples worldwide experience difficulty conceiving a child; a recent study indicates the overall burden of infertility worldwide has remained the same from 1990 to 2010 (WHO, 1992; WHO, 2012).

The motivation to become a parent and the value placed on the ability to procreate is important globally but varies between cultures. This is evidenced by the length and cost to which patients and their doctors are willing to go in order to conceive, and deliver a healthy baby. Generally, in the West today, the motivation for this is expressed as a wish for personal happiness and fulfilment; children become an additional source of enhancement to their parent(s) quality of life. Many couples choose also, to be voluntarily childless in their relationship; which is socially acceptable. They are not perceived as any less important within the family or amongst friends. However, in many African cultures, having a child is crucial for couple's personal identity both socially and culturally. In addition, the belief that having a child guarantees continuation of the family heritage, fulfilment of religious and societal expectations, and an asylum in old age is an important sentiment shared by many African societies irrespective of the country of origin (Okonofua et al, 1997). There are also financial implications to receiving and accessing treatment (Rouchou, 2013; Cui, 2010). Research showed the time spent by couples pursuing fertility care in USA is averagely 125 hours within an 18 month period (Wu et al, 2013). Although there are no data on the estimated time spent seeking medical treatment in African settings, it is expected that

time spent seeking treatment will come at a significant financial cost for the infertility couple.

Therefore, the problem of infertility spans beyond the clinical; it has psychological, socio-cultural and even religious implications in some communities with resulting consequences on the help seeking behaviour of infertile couples, including the choice and attitudes to treatment (Dutney, 2006; Okonofua et al, 1997; Berg et al, 1991). Although male factors contribute to about half of all cases of infertility, women are often held responsible for couples' inability to conceive bearing majority of the burden of treatments with accompanying distress and discomforts (Hammarberg & Kirkman, 2013; Berg et al, 1991). Women are also more likely to carry the psychological and sociocultural burdens of infertility.

Infertility is a recognized cause of anxiety, depression, marital discord and violence amongst couples (Ardabily et al, 2011; Antai & Antai, 2008; Castro et al, 2008). It accounts for more than half of patients seen in gynaecological clinic in African countries (Mascarenhas et al, 2012; Araoye, 2003; Larsen, 2000; Gerias & Rushwan, 1992). Stress worsens infertility and vice versa. The complexity of infertility-related stress and anxiety for couples is relevant that it cannot be isolated from infertility management as whole. Counselling in infertility offers the opportunity to explore, discover and clarify ways of living more satisfyingly and resourcefully when fertility impairments have been diagnosed, offering an opportunity to combat infertility associated stress, even when the cause of infertility is unknown (Van den Broeck et al, 2010; Facchinetti et al, 2004).

A study by Forsythe et al (2002), found that voluntary counselling and testing (VCT) for HIV/AIDS would cost the government US$6800 yearly, per health centre in Kenya. It was also found that integrating the counselling services into existing health centres significantly reduced the cost of VCT from $26 to $16 per client, which was further reduced to $8 when health centre staff are trained and hired to perform the counselling (Forsythe et al, 2002). Extending this approach of integrating infertility counselling with infertility management would be beneficial for those seeking treatments. However,

infertility treatment are not subsidised for the patients, thus the full cost of counselling fully rests on the patients, adding to the burden of illness. Thus the development a low cost programme would increase access to counselling for infertility patients.

Cognitive behavioural therapy (CBT) is a talking therapy used to manage psychological problems by changing the way you think and behave. It is an approach to manage anxiety and depressive disorders. Given the benefits and positive outcomes of counselling and Cognitive Behavioural Therapy upon the psychological wellbeing of infertile patients from scientific and social research collected from many parts of world, it would be interesting to explore and investigate if such positive effects and benefits would be applicable to patients experiencing infertility within an African setting. Therefore, the development of an intervention to manage the psychological morbidities associated with infertility that is complimentary and integrated with clinical and biomedical model of infertility management becomes essential to the provision of holistic care to patients. Ideally, this intervention would be holistic, patient- centred, empowering, culturally sensitive and easily integrated with standard infertility care (Richardson & Puskar, 2012; Rahman et al, 2015).

Dyer et al (2001) described a study in South Africa regarding women's expectations of infertility service. The results showed women were lacking in information regarding infertility treatments and management, which often contributed to the stresses and anxieties that these women face. Despite this knowledge, many infertility patients attend health facilities for treatment without infertility counselling due to lack of resources in human personnel and time in busy clinical settings. Counselling provides an opportunity to provide information which is fundamental for treatment and prevention.

Main Objectives

1. To develop a CBT based counselling intervention to improve the psychological health and wellbeing of men and women having infertility problems in Nigeria.

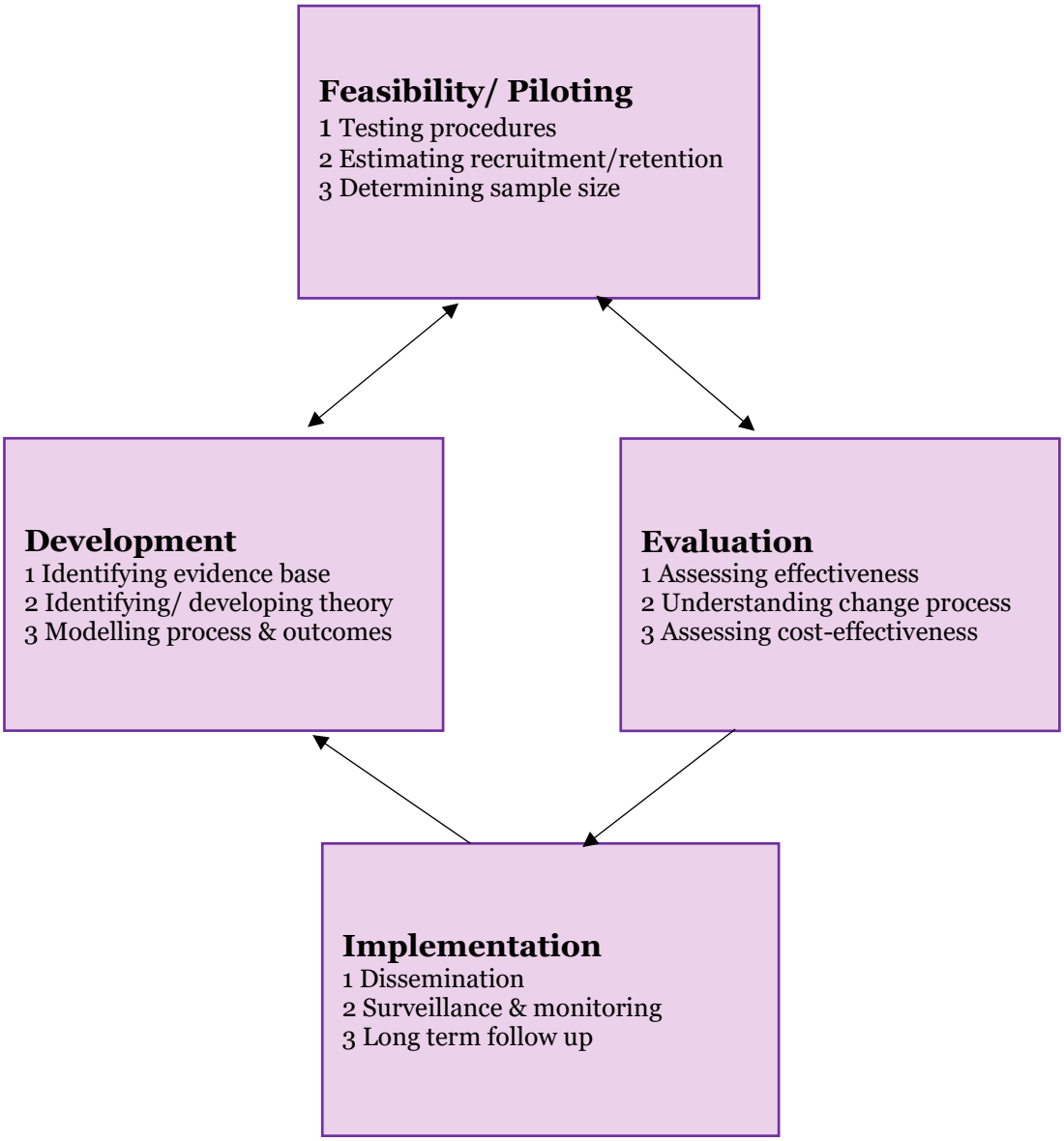
2. To describe the delivery of the intervention, including training and supervision, integrated with infertility management.

Development of FELICIA

The project used the MRC framework for development and evaluation of complex interventions (Craig et al, 2008). Four key elements for the development of complex interventions within health settings are described (Fig 3.2). These are the development, feasibility/pilot testing, evaluation and implementation. The development phase included a literature review of the psychosocial consequences of infertility (Table 1), identification of a theory-based approach to address these consequences, adaptation of the approach for infertility-related psychosocial distress, and strategies for integrating it within existing fertility-care services in Nigeria.

According to the Medical Research Council (MRC) it is important to ask certain questions when developing an intervention for health (MRC, 2008; Craig et al, 2008). The questions examine the clarity of the author(s) about the aims and outcomes of the intervention, to the practicability and cost effectiveness of the intervention. A lack of clarity about any of the question outlined in Fig 3.1 would require further development of the intervention (MRC, 2008). The updated MRC guidelines (MRC, 2008), when compared to the regulations from eight years before (MRC, 2000), were aimed at helping 3 main groups of people- the researchers, the research funders and the evaluators (Craig et al, 2008; MRC, 2000). The guidelines assist researchers by giving guidelines to select applicable methods to develop, and evaluate their interventions. It helps research funders understand the limitations on evaluation design, and the evaluators of the interventions to balance available evidence against methodological and practical restrictions.

Fig 4.1: Key elements of development and evaluation process according to MRC (Craig et al, 2008)



A good theoretical understanding of the health needs or requirement of the beneficiaries is required to the development of a useful, acceptable and sustainable intervention (Mascarenhas et al, 2012; Craig et al, 2008).

Further to the development of an intervention, an evaluation process is required to determine and amend implementation difficulties. The MRC

document (2008), recommends choosing multiple outcomes to be measured, unlike using a single primary data outcome. Also, flexibility is required when following an implementation protocol as the intervention will work more effectively if adjustments to factors within the local setting is permitted (Craig et al, 2008).

Fig 4.2: Questions to ask when developing and evaluating complex interventions (MRC, 2008)

1. Are you clear about what you are trying to do: what outcome you are aiming for, and how you will bring about change?
2. Does your intervention have a coherent theoretical basis? Have you used this theory systematically to develop the intervention?
3. Can you describe the intervention fully, so that it can be implemented properly for the purposes of your evaluation, and replicated by others?
4. Does the existing evidence – ideally collated in a systematic review – suggest that it is likely to be effective or cost effective?
5. Can it be implemented in a research setting, and is it likely to be widely implementable if the results are favourable?

Identification of evidence base - A review of the psychosocial consequences of infertility

We carried out a narrative review of scholarly articles from 2000 to 2016 through a literature search of major scientific data bases. The key findings of the literature review are outlined in Appendix 1. Although infertility affects both men and women, research shows infertility in a woman increases the possibility that her human rights will be violated and her negotiating power within the family and society will be greatly reduced as a result of her failure to conceive (Antai & Antai, 2008; Castro et al, 2008). In the majority of African communities, women's treatment in the community, their self-respect and understanding of womanhood depend on motherhood (Hollos et al, 2009).

Thus, the women experience social stigma, relationship problems and diminished emotional wellbeing due to infertility (Fledderjohann, 2012). Even in societies where women are socially and culturally empowered, the blame for infertility has been disproportionately attributed to women by their fellow women (Fledderjohann, 2012; Donkor & Sandall, 2007).

Critical analysis of literature identified four main themes as sources of psychological burden to infertility patients within the African context. They include:

1. Coping with the infertility diagnosis in relation to self, spouses and amongst family and friends (Antai & Antai, 2008; Hollos et al, 2009; Roudsari & Allan, 2011; Fledderjohan, 2012).
2. Dealing with demands of infertility treatments which have physical, social and financial implications (Cui, 2010; Wu et al, 2013; Rouchou 2013).
3. Understanding why treatments fail and coming to terms with it socially and in relation to personal faiths (Van den Broeck et al, 2010; Fledderjohan, 2012; Bokaie et al, 2016).
4. Knowledge and attitudes toward alternatives to childless including adoption (Ofovwe & Agbontaen-Eghafona ,2009; Oladokun et al, 2009; Omosun & Kofoworola, 2011)

Identification of the theoretical underpinnings of the FELICIA intervention:

There are various psychological interventions for infertility used in the management of psychological problems of infertility (Boivin, 2003). The rationale for the development of an intervention for management of infertility-related psychological distress at this stage is not to increase pregnancy rates (although welcomed), but to improve patient wellbeing. Examples of other forms of psychological interventions, with their own theorical bases, include educational therapy and psycho education, supportive therapy, interpersonal therapy, and cognitive therapy which includes CBT. These have all been explained in details in Chapter 2, pages 55-58. These therapies have been found to be beneficial for various infertility patient groups, irrespective of gender, as well as helpful in establishing collaborative working relationships

with the health workers (Wischmann et al, 2001; Neugebauer et al 2006; Neugebauer et al 2007; Cousineau et al, 2008; Noorbala et al, 2009; Richardson & Puskar, 2012; Markowitz, 2014).

Amongst infertility patients, CBT proved to be of better benefit than pharmacological treatment of infertility-related depression, improving the outcomes of up to 79% of patients (Berga et al, 2003; Faramarzi et al, 2008; Buck-Louise et al, 2014). Counselling in infertility (as in other bio-psychological impairments such as cancer) offers the opportunity to explore, discover and clarify ways of living more satisfyingly and resourcefully when fertility impairments have been diagnosed, offering a pathway to reducing the stress levels of the inflicted, even when the cause of infertility is unknown (Van den Broeck et al, 2010; Facchinetti et al, 2004). CBT has also been found to reduce infertility-associated stress in patients undergoing IVF treatment, even after failed IVF episodes (Peterson & Eifert, 2011; Facchinetti et al, 2004).

Cognitive behaviour therapy (CBT) was chosen as the theoretical underpinning of FELICIA intervention. CBT is a structured exchange of mind-sets and viewpoints between therapist and client that aims to modify unhelpful and unhealthy thinking (cognitions) and behaviour displayed by client's feelings and actions (behaviour). It has been applied to psychological conditions such as anxiety and depression (Hunot et al, 2007; Cape et al, 2010). It has also been incorporated into public health programmes to deal with lifestyle problems such as smoking, obesity and promoting breastfeeding (Sykes & Marks 2001; Golay *et al.* 2004; Zafar et al 2016).

Cognitive Behavioural Therapy (CBT) challenges thoughts. It helps individuals to recognise, address and correct inaccurate and often unhealthy beliefs and thoughts, replacing them with positive helpful, healthy thoughts, beliefs and behaviour. It is a structured, problem-oriented intervention focused on solving a present problem, and has become a treatment of choice for various mental health conditions (Blenkiron, 1999; NICE, 2006; Rupke et al, 2006; NICE, 2009). Counselling in infertility using CBT techniques offers the opportunity to explore, discover and clarify ways of living more satisfyingly and resourcefully when fertility impairments have been diagnosed, offering a

pathway to reducing the stress levels of the inflicted, even when the cause of infertility is unknown (Van den Broeck et al, 2010; Facchinetti et al, 2004).

FELICIA was developed as an adaptation of the Thinking Healthy Programme (THP). THP is a CBT-based intervention for perinatal depression, available as a supplement to the World Health Organization's mhGAP Intervention Guide (mhGAP-IG), to be used in non-specialized health-care settings (WHO, 2015). One of the priorities identified in the mhGAP guideline is depression in the perinatal period (WHO, 2010).

The Thinking Healthy Programme

The Thinking Healthy Programme (THP) was developed as a solution by providing detailed step by step instructions on how to implement the guidelines contained in the mhGAP-IG, for the management of perinatal depression. The programme was created as a manual to supply an unmet need for the World Health Organization's mhGAP Intervention Guide -mhGAP-IG. The mhGAP-IG guidelines were developed based on scientific evidence to identify and manage priority mental health conditions (WHO, 2010). According to the authors of WHO Thinking Healthy Programme document, the mhGAP-IG explains in detail what to do when assessing and managing people with mental, neurological and substance use disorder in busy clinical settings, but it does not describe how manage the mental health conditions identified in the mhGAP document (WHO, 2010; WHO, 2015).

The intention of THP is to integrate maternal and child health programmes in primary care. The manual consists of instructions of how health workers can use the mhGAP guidelines for the management of perinatal depression. The THP manual is aimed at community workers who have no specialization or previous knowledge and experience of mental health care within non-specialized health care settings. The programme uses Cognitive Behavioural Therapy (CBT) ideologies to offer an intervention for women experiencing post-natal depression. It seeks to change unhelpful thinking styles and consequent undesirable behaviour by using 3 key steps. These steps are represented by culturally appropriate illustrations that help patients easily identify and relate to the concepts (Fig 4.3; 4.4; 4.5.). The 3 steps are:

a) Learning to identify unhealthy ways of thinking.
b) Learning to replace unhealthy thinking with healthy thinking.
c) Practising and acting healthy thinking.

Like the THP, FELICIA uses these core principles of intervention. The three steps of THP are used to deliver health education and psychotherapy to infertility patients. The method promotes easy explanation of the treatment options and exchange of information by gaining an insight to patient's perspectives to the infertility journey, which is central to the therapeutic principle of talking therapies (Bloch et al, 1979; Richardson & Puskar, 2012).

Fig 4.3: Step 1 of the 3 steps of Thinking Healthy Programme (2015)

Picture A

Step 1

Learning to identify unhealthy thoughts

Ask the mother to focus on picture A, the symbol for this step. Explain that in order to promote healthy thinking, it is important to be aware of the common types of unhealthy thinking styles. By conducting research on many thousand of ordinary people like us, scientists have defined the following types of unhealthy thinking styles. Make the mother familiar with the symbol below for learning to identify unhealthy thoughts and go through the following examples in Box 1. Tell the mother that we will talk a bit more about such thoughts and their effects later in the session.

Fig 4.4: Step 2 of the 3 steps of Thinking Healthy Programme (2015)

Picture B

Step 2

Learning to replace unhealthy thinking with positive or healthy thinking:

Ask the mother to focus on picture B. Explain that identifying the above unhealthy thinking styles enables us to examine how we feel and what actions we take when we think in this way. The programme will help the mother question the accuracy of such thoughts and suggest alternative thoughts that are more helpful. With practice the mother can learn to challenge and replace unhealthy thinking with healthy thinking. Make the mother familiar with the symbol for learning to replace unhelpful or unhealthy thinking with helpful or healthy thinking.

Fig 4.5: Step 3 of the 3 steps of Thinking Healthy Programme (2015)

Picture C

Step 3

Practice healthy thinking and acting:

Ask the mother to look at picture C. Explain that the programme suggests activities and practice work to help mothers to practice thinking and acting in a healthy manner. Carrying out these activities is essential for the success of the programme. Mothers will receive health education and other materials tailored to their individual needs to help them progress between sessions. Help the participant become familiar with the symbol for learning to practice healthy thinking and behaviour.

Step 1: Learning to identify unhealthy thinking:

In order to promote positive thinking, it is important to be aware of the common types of unhealthy thinking styles that gradually develop as a result of life problems or experiences. Using carefully researched and culturally appropriate illustrations, patients are educated about such unhealthy thinking styles and learn to identify them.

Fig 4.6: Step 1 of the 3 steps of THP in FELICIA (2018)

Step 1

Learning to identify unhealthy thoughts

Ask the patient to focus on picture A, the symbol for this step.

Explain that in order to promote healthy thinking, it is important to be aware of the common types of unhealthy thinking styles. By conducting research on many thousands of ordinary people like us, scientists have defined the following types of unhealthy thinking styles; these are highlighted in Box 2.2. You can go through the examples in Box 2.2.

Make your patient familiar with the symbol below (Picture A) for learning to identify unhealthy thoughts. Tell the patient that we will talk a bit more about such thoughts and their effects later in the sessions.

Picture A

Step 2: Learning to replace unhealthy thinking with helpful thinking.

Identifying such unhealthy thinking styles enables patients to examine how they feel and what actions they take when they think in this way. By learning to identify unhelpful thoughts, patients can question the accuracy of such thoughts and suggest alternative, more helpful ways of thinking

Fig 4.7: Step 2 of the 3 steps of THP in FELICIA (2018)

Step 2

Learning to replace unhealthy thinking with positive or healthy thinking

Ask the patient to focus on picture B. Explain that identifying the above unhealthy thinking styles enables us to examine how we feel and what actions we take when we think in this way. The FELICIA programme will help the patient to question the accuracy of such thoughts and suggest alternative thoughts that are more helpful. With practice the patient can learn to challenge and replace unhealthy thinking with healthy thinking.

Familiarise your patient with the symbol (Picture B) for learning to replace unhelpful or unhealthy thinking with helpful or healthy thinking. This symbol will be used in many instances throughout the counselling sessions

Picture B

Step 3: Practicing thinking and acting healthy

The intervention suggests activities to help the mother (in the case of FELICIA, the infertility patient) to practise helpful thinking and more helpful behavior. Carrying out the recommended activities is essential for the success of the programme. Participants receive health education and other materials tailored to their individual needs to help them progress between sessions. A Health Calendar is used to assist the mothers in monitoring these activities in between sessions.

Fig 4.8: Step 3 of the 3 steps of THP in FELICIA (2018)

Step 3
Practice healthy thinking and acting
Ask the patient to look at picture C. Explain that the programme suggests activities and practice work to help patients going through infertility to practice thinking and acting in a healthy manner. Carrying out and being involved in the required activities is essential for the success of the programme.
Patients will receive counselling sessions and other materials tailored to their individual needs. This is to help them progress between sessions.
Help the participant become familiar with the symbol for learning to practice healthy thinking and behaviour (Picture C).

Picture C

The main concept in CBT is that you feel the way you think, and works on the principle that you live more happily and productively if you are thinking in helpful ways. In this intervention, patients are encouraged to assume responsibility about the way they feel by taking control of their thoughts and actions into thinking healthy. It is encouraged to think flexibly by avoiding a "must", "should" or "have to" approach to dealing with issues regarding infertility problems.

The narrative approach: incorporating stories and analogies in CBT

Stories and analogies are an effective way to pass on information and are encouraged by cognitive behavioural therapist as a means of challenging unhelpful thinking behaviour, enhancing rapport and promoting the personal impact during therapeutic talking sessions (Blenkiron, 2005). The stories in FELICIA use ideas from true life events derived from day to day relations with patients, colleagues and friends with fictional characters. It utilises culturally appropriate stories and analogies to describe and buttress healthy and unhealthy thinking styles. Blenkiron (2005) explains the significance of inventing and developing stories as a skill for CBT through ideas from clinical supervisions, educational workshops or information volunteered by the client.

The stories in FELICIA relate the same situation in 2 different perspectives – an unhealthy unhelpful think style and a healthy helpful one (Fig 4.9). Thus, FELICIA uses stories and analogies to:

a) Identify the unhealthy ways of thinking in the story A
b) Replace unhealthy thinking with helpful & healthy thinking in story B
c) Practise and act healthy thinking by relating to and making good choices highlighted in the stories and analogies.

The use of stories is central to many African cultures as a culturally acceptable means of passing information for generations. It discourages feelings of stigmatisation by the patient as discussions are initially held in third person before being related to the patient's personal experiences. This makes it easier for patients to face their reality; at the same knowing that they are not alone in this struggle.

Fig 4.9: Using stories and Analogies to discuss thinking healthy in FELICIA

Box 5.1: John & Rita's story

Rita and I have been trying for a child of our own for 18 months. At first, we thought it would happen naturally and we did not want to stress about it. But after some time we decided to seek medical help.

Rita and I had gone through a series of test to find the cause of our infertility. The doctor advised that we both take some vitamins to help prepare us for pregnancy. But in addition to Rita's vitamins, she needed to take some other drugs. We are told they contain hormones. Poor Rita, the drugs make her feel awful. She is moody all the time. I feel for her really; after all, I had to do was give a sample. She has endured so many blood tests, ultrasounds and some very painful procedures! All this happens in private too; we have to carry on like nothing is happening. Enduring month after month of constant disappointments is enough to make any one moody.

Well, what can we do? We just need to keep trying. I try to say nothing when she is upset. To be honest, I really don't know what to say and fear I might just say the wrong thing. I hope the medication works. I believe that is the only thing that can make her happy again.

Box 5.2: John & Rita's story

Rita and I have been trying for a child of our own for 18 months. At first, we thought it would happen naturally and we did not want to stress about it. But after some time we decided to seek medical help.

Rita and I had gone through a series of test to find the cause of our infertility. The doctor advised that we both take some vitamins to help prepare us for pregnancy. But in addition to Rita's vitamins, she needed to take some other drugs. We are told they contain hormones. Unfortunately, the drugs make Rita feel awful. She is moody all the time. I feel for her really. I had to give a sample at the clinic and I know how awkward that felt for me. So I understand how hard it must be for her after having endured all the different tests, some very painful. I think the way we carry on like nothing has happened makes it harder to cope with the disappointment.

I agree we need to seek some treatment but it is not fair for Rita to carry the burden alone. I will go with her for the next consultation and discuss this with the doctor. Meanwhile, I think we should go to that restaurant I took her when we were courting. She loved it there. That should make her happy.

Box 5.4: John and Rita's helpful thinking and actions

	Situation (Activating Event)	**Thoughts and Feelings (Beliefs)**	**Action (Consequences)**
Helpful 	John is unhappy about Rita's side effects from infertility treatment	John **shares** the emotional burden with Rita *I agree we need to seek some treatment but it is not fair for Rita to carry the burden alone* This helps John **understand** how Rita might be feeling.	John is **dedicated** to helping Rita get better by **getting the help** they need. *I will go with her for the next consultation and discuss this with the doctor.* John finds **other ways to make Rita happy** while they seek help. *…I think we should go to that restaurant … She loved it there. That should make her happy.*

Box 5.3: John & Rita's unhelpful thinking and actions.

	Situation (Activating Event)	**Thoughts and Feelings (Beliefs)**	**Action (Consequences)**
Unhelpful 	John is unhappy about Rita's side effects from infertility treatment	John **feels sorry** for Rita but is **afraid** to discuss it. *To be honest, I really don't know what to say and fear I might just say the wrong thing"* *I believe that is the only thing that can make her happy again* (**Thinking in Extremes**)	*I try to say nothing when she is upset.* John is **avoiding the situation** by saying nothing. This will make Rita feel more alone **(Isolation).**

Modelling the intervention

Based on critical literature review, we identified the four main sources of psychological burden for infertility patients, especially within African settings in Table 3. How we think of ourselves or how believe we should, behave and act, which is our self-concept, determines the magnitude of our perceptions towards a problem. Self-concept is defined as the totality of or beliefs, preferences, opinions and attitudes towards our personal existence (Jhangiani & Tarry, 2014; Stagnor, 2011). Thus, dealing with the psychological morbidities associated with infertility should be viewed personally and in relations to others around the patient, which could directly or indirectly contribute to the patients' despair. In addition, we also met with the developers of THP to discuss ideas of adapting the programme to meet the needs of infertility patients.

Based on this understanding in conjunction with the developed themes, the FELICIA counselling modules were produced (Table 4.1):

1. A compulsory (introductory) module, which explains FELICIA as an intervention
2. Four optional counselling modules designed and tailored to patient's individual needs.

From the identified FELICIA modules, 10 pragmatic counselling session were derived, out of which patients attend six counselling session to be delivered at the frequency of one session per week. The counselling session consist of 2 compulsory sessions from the compulsory module at week 1 and week 6. It also consists of 4 sessions to be picked from the optional modules, according to patients' individualised needs (Fig 4.10).

Each counselling session has learning objectives and counselling procedure is explained in a step by step task-based approach of delivery (Table 4.1). This method standardises FELICIA counselling for health-workers, ensuring everyone carries out the intervention in the same way.

Tailoring the intervention to individual client needs

After discussing the patient's infertility journey and expected outcomes, the health-worker assists the patient in identifying training sessions tailored to patient's need. This is done with the full collaboration of the patient; the health-worker explains how often the sessions will take place. Session 1 and 10 are compulsory for all participants. With the patient's collaboration and full engagement, the health worker picks 4 sessions from session 2 – 9 tailored to patients' individual needs (Fig 4.10).

Fig 4.10: Diagram of a guide to choosing counselling sessions (Extracted from the FELICIA manual)

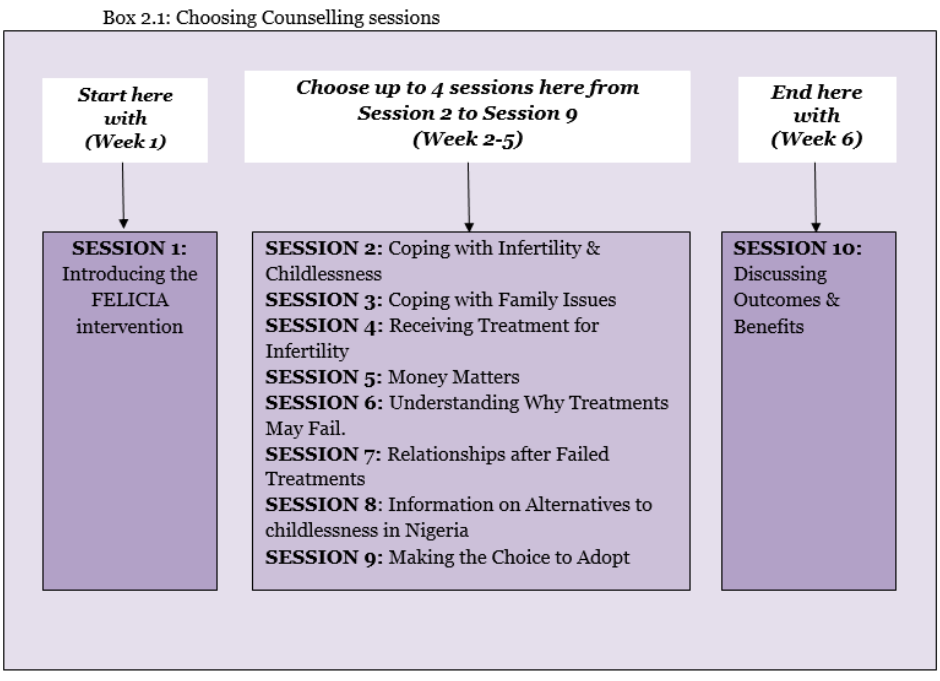


Table 4.1: FELICIA Counselling sessions and Learning Objectives

	SESSION	Learning Objectives of the session
Compulsory Module O: Introduction	**SESSION 1:** Introducing the FELICIA intervention	1. Introduce the FELICIA intervention and objectives 2. Discuss patient's infertility journey and expectations. What is your patient expecting? Is this realistic? What do you expect from your patient? Are they willing to engage? Discuss homework and its importance. 3. Discuss your patents expected outcomes from the intervention. Discuss the purpose and objectives of the intervention.
Module I: Coping with infertility	**SESSION 2:** Coping with Infertility & Childlessness	1. Discuss infertility causes. 2. Discuss how common infertility is in our society. Focus on patient's causes (if known) 3. Discuss patient's ways of coping with infertility and childlessness
	SESSION 3: Coping with Family Issues	1. Discuss relationship with spouse and family 2. Discuss interactions with friends. 3. Making the most of your support network.
Module II: Treatments	**SESSION 4:** Receiving Treatment for Infertility	1. Discuss patient's ways of coping with the physical demand of infertility treatment 2. Discuss keeping healthy while dealing with infertility treatments (mind & body)
	SESSION 5: Money Matters	1. Addressing patient's ways of coping with the monetary cost of infertility tests and treatments. 2. Discuss patient's ways of coping with work life and infertility treatments

Module III: Unsuccessful treatments	**SESSION 6:** Understanding Why Treatments May Fail	1. Discuss patients understanding of why treatment may fail 2. Discuss patient's coping strategy with unsuccessful treatment
	SESSION 7: Relationships after Failed Treatments	1. Discuss relating with spouse after failed treatment. 2. Discuss interaction with friends and family in the event of failed treatments.
Module IV: Alternatives	**SESSION 8:** Information on Alternatives to childlessness in Nigeria	1. Discuss patients understanding of alternatives to childlessness such as adoption, surrogacy and using sperm donors. 2. Discuss patient's choices and factors that affect making the right decision for them. 3. Discuss access to adoption, surrogacy and sperm donor services in Nigeria
	SESSION 9: Making the Choice to Adopt	1. Discuss patient's journey to the choice to adopt. 2. Discuss patient ways of telling spouse about her/his decision Discuss patient's ways of coping with family and friends' perceptions including judgement and opinions
Compulsory Module O: Outcomes	**SESSION 10:** Discussing Outcomes & Benefits	1. Discuss Counselling Outcomes and Benefits for Patient. 2. Making the most of your support network 3. Making a lasting positive change

Delivery of the intervention:

Task Shifting Approach

Task shifting is a process of delegation whereby tasks are moved, where appropriate, to less specialized health workers in order to maximize the efficient use of health workforce resources (WHO, 2006; Chang, 2009). Task shifting provides a solution to the scarcity of trained mental health professionals within resource poor settings in Africa. It also provides a low-cost solution to tackling gaps in health care services, especially in developing and resource limited societies.

FELICIA as an intervention uses the approach of task shifting by shifting role from often expensive and short-staffed specialised psychiatrist and CBT therapist in African health settings to trained nurses and community health workers to deliver counselling using CBT techniques. In infertility clinics, patients are in regular contact with nurses and community health workers who will be trained to deliver the intervention. This promotes skill retention by health workers, sustainability of the programmes and increased access to mental health care for the patients. It also provides an integrated continuum of holistic care for infertility patients.

Guiding Principles

The guiding principles to the delivery of FELICIA were as follows:

1. **Holistic Care**

There is a perception that western medicine, also known as conventional tends to concentrate on the pathology of the disease or disorder, thus not caring for the patients as a whole (Chun, 2012). Unlike conventional medicine that tends to focus on a specific diagnosed condition, the holistic approach to care embodies the physical, mental and social health of patients. According to Woodward (1993), in addition to its multifaceted focus, holistic care must be affordable, effective, and safe and prevention oriented. It should also be acceptable collectively, benefit the environment, compliment

conventional medicine, as well as have an organised system for training health care providers (Woodward, 1993).

Infertility is a condition that affects not only the reproductive potential of those who suffer it; it also has social, psychological, and economic implications on those affected. As such in the care of infertility, this holistic approach is essential for total care of patients. This requires a multidisciplinary approach that helps men and women who suffer infertility live more satisfying while undergoing treatments; and after failed treatments.

2. Patient-centred

The objective of a patient-centred approach of healthcare is to provide the best care to the patient, which includes the utilisation of all available resources (American College of Physicians, 2010). This approach is most logical to achieve an equity based, accessible and affordable care for all, but it requires retraining healthcare personnel to acquire tolerance, cooperation and better awareness and utilisation of verified resources in health care (Sanjeev, 2012).

Counselling care is tailored to the individual needs of the patient at a point in time. It is not a one size fits all programme. Infertility patients already have a lot to deal with on a daily basis outside of their diagnosis; discussions of irrelevant issues is not only time wasting but distressing. Thus counselling is focused on patients' needs by providing 10 different counselling sessions that patients can choose from in relation their individual needs.

3. Community-oriented

Community and community participation involve social and emotional influences constructed in physical or geographical locations (spaces), movement between the spaces, as well as the qualities of the described space (Day et al, 2016). Moreover, people who are more socially connected live longer and experience better mental and physical health with a 50% greater likelihood of survival than their isolated counterparts (e.g., Holt-Lunstad et al., 2010). According to Grano et al (2016), implementing stress-reducing care in co-operation with family members, the community, combine with a multidisciplinary approach to care, could improve the psychiatric symptoms, as well as improve help-seeking behaviour of those affected.

Studies show an association between decreased social support and both physical and mental health, as well as the need to access social and mental support in clinical care (Strine et al, 2008, Salihu et al, 2017). Studies also show that the participation of the community offered an insight in the community's needs and concerns, providing an understanding of context specific conditions and impacts (den Broedera et al, 2017)

The FELICIA programme has been designed such that it can be adapted to be used within the community by all health care professionals at all levels. This is essential because stress and stigma related to infertility originate from community relationships as a result of an unmet expectations. The pictures, stories and analogies are based on day to day interactions within communities, both urban and rural; thus relatable while providing counsel, health education and information as well as psychotherapy for infertility patients (Blenkiron,2005; WHO, 2015).

4. Culturally-sensitive

Cultural connections are dynamic, constantly modifying and adapting, but influenced over time by self-concept, socio-economic status and traditional considerations (Kidd et al, 2016). Culturally sensitivity in care, facilitates beneficial outcomes from health services; it also reduces inequalities in access to health services because it considers and integrates patient's cultural beliefs into patient care (Douglas et al., 2011; 2014; Yilmaz et al, 2017). The perception of the inability to conceive in many African societies stem from the cultural expectations and values placed upon having a biological child. In many studies, it had been shown repeatedly that cultural expectations are a major source of stress and stigma for both infertile men and women (Antai & Antai, 2008; Castro et al, 2008; Sembuya 2010). Cultural sensitivity during counselling is essential on both sides of the infertility coin. On one hand, it acknowledges the importance patients place upon the cultural meaning of having one's own child. On the flip side, it introduces patients to a different way of thinking about having infertility, challenging the status quo, thereby bridging the gap between the familiar and unfamiliar solutions to infertility.

5. **Empowering**

Empowerment involves a process of giving control and ability to value own decision to an otherwise marginalised person or group or to gain control over one's own life from a tradition, culture or belief that causes a surrender of power or marginalisation (Rappaport, 1981; Sadan, 1997; Zimmerman, 2000; Moran et al, 2017). Empowerment focuses on strengths, viewing individuals as having competencies and independence, yet requiring opportunities and resources in the external environment in order to optimise those potential opportunities by providing the needed resources and collaborating with relevant professionals (Moran et al, 2017).

The FELICIA programme aims to encourage the participant to engage in the discussions with the health care team during counselling sessions by challenging current negative beliefs and perceptions. This will help develop new positive ways of thinking about a problem. The changes in thinking and perception are directed towards positive outcomes which are empowering. The empowerment comes from the participant actively taking ownership of their thoughts towards healthy living, hence a healthy reproductive life.

The FELICIA intervention pack

This consists of a counselling manual for health-workers, a patient workbook for patients and the recording book for the health-worker/ counsellor.

1. **Counselling manual for health-workers**

The counselling manual is divided into 3 sections- an introduction section that explains in detail about the intervention objectives and methodology, the intervention section which consist of 10 counselling session, and a third section that highlights difficult situations that may arise and how to deal with them .

In section 2, each session highlights its learning objectives in Table 4.1 and describes a step by step guide to completing the counselling tasks. These counselling tasks start with the health-worker welcoming the patients and collecting the mood chart which would have been previously given and filled

out by the patient in the preceding week (Fig 4.11). The mood chart serves as an indicator and update for how the patient's mood has been recently. It is also an ideal conversation starter. Next, the objectives of the session are addressed and patients are given two stories to read. Each story describes a health and an unhealthy thinking style to a particular situation (Fig 4.8). Patients are then encouraged to use the 3 steps of thinking healthy to identify, replace and practice healthy, helpful thinking styles, discussing and relating these stories and analogies to their own current situation (Fig 4.8). After discussion, the patients and the health worker agree to a specific homework that helps the patient practise the learning objectives of that session. A summary of the discussion is agreed with the patient before ending the session. This ensures an agreement between the health-worker and patient regarding the expectations and outcomes of that session as well as the subsequent sessions.

2. **The patient workbook for patients:**

The structure of the patient workbook is designed to follow through with the activities and homework of each session. Patients are encouraged to write in their interpretations and thoughts in line with the learning objectives for each session. The workbook contains the mood chart and homework can be completed in it. The patient workbook is ideal for literate patients who can read the instructions and write their responses, during and after each weekly session. Hence for illiterate patients, the use of the workbook is optional; the health-worker discusses the instructions and writes the patients' responses in the book. Health-workers are trained to record responses in patients own words and avoid abbreviations or interpreting patient's response in other words. If the health worker is unsure of what the participant means, he/she should ask the patient to elaborate or clarify responses and record accordingly.

3. **The recording book:**

The recording book for the health-worker is a diary of events for each session where they can record their own observations, summarise the activities during the counselling sessions and make notes of important tasks or homework for individual patients. The recording book is purposed for the health worker, updates about previous discussions in past sessions, and

indicates the upcoming tasks and activities in line with the learning objectives for each session.

Fig 4.11: Mood chart (Extracted from FELICIA manual)

Task 2

Update from last session
After your patient is settled in the room, assess the mood chart.

Example of a patient's mood chart

MOOD CHART	Very Good 	Good 	Neither good nor bad 	Bad 	Very Bad 
Saturday		x			
Sunday	x				
Monday			x		
Tuesday			x		
Wednesday			x		
Thursday				x	
Friday					x

Try to deduce how the week had been and ask about this. You can start by saying something like:

"It looks like you had a bad week. Is everything ok? Do you mind sharing your experience?"

They might have something to discuss with you then. Remember that people usually have more than one problem. Try to keep your discussion to issues regarding their infertility problems.

Training and Supervision:

This intervention is self-explanatory and requires minimal training. However, there is the need to maintain the structure of how each session is expected to be delivered. This ensures that all FELICIA counsellors are delivering the intervention in the same way, makes the outcomes more measurable, and helpful in evaluating effectiveness of the intervention. In addition to this, each patient, irrespective of who they meet for counselling, are sure of receiving the same intervention.

A two-day course will be provided to study the manual and explain the process. The FELICIA counsellors are familiarised with the mhGAP guidelines of identifying mental health conditions, especially anxiety and depression (WHO, 2008; WHO, 2010; Dua et al, 2011). The 'counsellors' will also be involved in role plays to demonstrate how they would deliver the intervention practically, in real life situations. They are expected to be supportive and non-judgemental. During this training, all those who participate will be observed and those who possess appropriate interaction skills and qualities of empathy and objectivity will be identified and selected to deliver the FELICIA intervention.

More importantly, clear guidelines are made available to identify and refer severe cases appropriately. Patients who are severely depressed or suicidal will be referred immediately for specialist psychiatric assessment and treatment as required.

Discussion and Future Directions

FELICIA is a pragmatic intervention suitable for the African context utilising cognitive behaviour strategies and narrative approaches, and delivered by a non-specialist. It is designed to bridge the gap between clinical and psychological management of infertility using an integrated holistic care approach, promoting a multi-disciplinary approach to infertility management.

Cognitive Behavioural Therapy (CBT) has the potential to benefit for the psychosocial management of infertility as a whole. Although research in this area is scarce, especially in low- and middle-income settings, Faramarzi et al (2008) carried out a randomised controlled trial in Iran and the results showed that CBT proved to be more effective than pharmacological treatment of infertility related depression, improving the patient outcomes in 79.3% of participants. The study compared the effectiveness of CBT with fluoxetine for treatment of anxiety and depression amongst 89 patients with infertility- the resolution of depression was 50% in the Fluoxetine group, 79.3% in the CBT group and 10% in the control group (Faramarzi et al, 2008). The reduction in infertility-associated stress has also been demonstrated in women undergoing

IVF treatment, even after failed IVF episodes (Peterson & Eifert, 2011; Facchinetti et al, 2004). The relief of psychological stress may also have physiological benefits. Berger et al (2003) documented recovery of ovarian activity in 7 out of 8 women with functional hypothalamic amenorrhea who attended CBT over a 20-week period.

The intervention is designed to be delivered by non-specialists especially in the African settings where there is a severe lack of specialist mental health professionals. While detailed feasibility testing will take place in these settings, we anticipate potential challenges that could be encountered in delivering FELICIA. The section 3 of the FELICIA manual covers in more detail approaches to dealing with such difficult situations. The FELICIA intervention recognises that counselling is a highly subjective experience and no two experiences are exactly the same. However, for the sake of standardising care, the health workers are advised of the chosen approach by this programme to in dealing with such difficult experiences.

An important challenge is when health workers come across patients with signs of severe depression and anxiety. This can be identified using the mhGAP intervention guide (WHO, 2008; WHO 2010). Health workers delivering the intervention are made familiar with the mhGAP guidelines during the FELICIA training programme. Patients with severe symptoms and/or signs, including suicidal intents are to be taken very seriously and urgently referred to the local psychiatric facilities.

Another potential challenge is when an illegal or criminal act has been disclosed during discussions. Patients are advised by the health worker before detailed discussions begin that they are obliged under the law to report any disclosed criminal activities to appropriate authorities in order to protect patients or others from danger. It is understandable that the stigma of infertility in African societies can drive patients to desperate measures, but this cannot be allowed to justify crime. However, the health worker's role is not to be judgemental but to find a healthy balance between what is ethically and morally right while providing holistic care to the patient.

It is also common for infertility patients in African societies to try multiple solutions to their infertility problem at the same time. Patients may employ traditional healers, herbal treatments as well as religious means while attending the hospital for clinical management of infertility. The ultimate goal is conception and childbirth; for the patient, any means necessary is justified. In the FELICIA manual, this is referred to as *"Multi-agency treatments"*. The FELICIA intervention aims to help patients to think in helpful ways, enabling them make the right decisions about their health and treatments. One of the ways it does this is by correcting unfounded fears or ideas patients might have regarding the causes of infertility and about infertility treatments by offering facts without disregarding patients' beliefs or ideologies.

Alternatively, some patients may find it difficult accepting new ideas such as the FELICIA intervention. Patients are advised that this intervention is a self-help style to counselling, using task based and homework to deliver therapy. Hence, patients have to be willing to make the changes and engage for the intervention to work. If they are unwilling, then they are not suitable for the technique used in FELICIA as an intervention for managing psychological problems associated with infertility.

FELICIA is an intervention with the potential to bridge the identified gaps between the clinical, psychosocial and management of infertility, thus providing holistic care for infertility patients. The future objective is to implement FELICIA as an intervention to be integrated with infertility care in resource poor settings. The next stages of the MRC framework for the development and evaluation of complex interventions will be applied to test, evaluate and implement FELICIA (Craig et al, 2008). As mentioned in the development section of this article, the pilot RCT of the FELICIA is taking place in Nigeria. If FELICIA is shown to be feasible, a full trial will be carried out and evaluated. Also, a cost effectiveness study will be developed to demonstrate the benefits of the intervention over the costs incurred. However, FELICIA has been designed to be delivered by non-specialists, thus it is anticipated that the cost will be low and adaptable to large scale implementation. In addition, an internet self-help version of the intervention

will be considered in future plans for FELICIA, enabling a broader access to those who require it.

Chapter 5:
A Feasibility Study for a Randomised Trial of FELICIA, an Intervention for the Management of Infertility Induced Psychological Distress

Introduction

The FELICIA Study is a feasibility study for a randomised trial of an intervention based on Cognitive Behavioral Therapy (CBT) for management of the psychological effects of having infertility. This counseling package is to be offered as an intervention to help couples deal with their life stressors and change their way of thinking and behavior. It helps couples to make informed choices and the best decisions with a rational mind and not as a result of societal pressure and expectations.

Psychological interventions, either by individual, couple or group sessions have been found to be effective and beneficial to reduce infertility related distress, leading to a decline in anxiety and depression (Domar et al, 1990; Greil, 1997; Terzioglu, 2001; Boivin, 2003; Lemmens et al, 2004; de Liz & Strauss, 2005). A review by Boivin (2003) examined the effect of psychosocial interventions on well-being of infertility patients. They found showed that in 48.6% (n=17/35) of studies, there were positive effects derived from the considered interventions (Boivin, 2003). Although the results showed pregnancy rates were unlikely to be affected by the interventions, the psychosocial interventions revealed a reduction in personal negative affect and interpersonal functioning socially and in marital relationships (Boivin, 2003; Cousineau & Domar, 2006). Moreover, the changes seen were more established individually as a reduction of negative psychological effects (Boivin, 2003).

Cognitive-behavioral methods have been used to improve wellbeing of infertile couples for over 3 decades, since 1987 (Domar et al, 1990; Lemmens et al, 2004; Cousineau & Domar, 2006). An important strength of CBT is that it changes unhealthy thinking styles and consequent undesirable behaviour,

and thereby motivates patients to change thinking styles and behavioural lifestyles in positive healthy and helpful ways. CBT also teaches the approach that treats a thought/ belief as a hypothesis, not a fact, to be tested as true or untrue thereby stimulates objective thinking.

CBT has been found to have has multiple potential benefits in infertility. Researchers suggest that it is of better benefit than pharmacological treatment for infertility-related depression, improving the patient outcomes as demonstrated by Faramazi et al (2008). There may be a positive effect of fertility by restoring ovarian activity, which was suggested by a small study where 7 out of 8 patients with ovarian failure after 20 weeks of CBT interventions (Berger et al, 2003). Recommendations have also been made for women having difficulty getting pregnant to consider stress-managing techniques as research showed a two-fold increased risk of infertility in stressed women (Buck-Louise et al, 2014).

Generally, CBT gives couples a better negotiating power in reasoning, providing improvements in the general health status of patients while undergoing treatments for infertility. The World Health Organisation defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". Thus, the management of infertility should be approached through this concept of not only focusing to reverse the aetiology of a known illness, but to treat other aspects of ill health that come as a result of an inability to conceive a desired child. This includes their mental and psychological wellbeing. The current state of health and wellbeing of individuals is influenced positively or negatively, by their physical, mental and social abilities to satisfy the life needs corresponding to their age, culture, and other expected responsibilities (Bircher, 2005). So whilst the CBT-based intervention does not guarantee that pregnancy will be achieved at the end of the intervention, it may provide a significant improvement in the quality of life of couples while undergoing infertility treatments.

The FELICIA Programme

The FELICIA programme is a CBT-based counselling intervention developed to manage psychological distress associated with infertility. It uses the theoretical underpinning of CBT to help patients identify and replace negative unhelpful thoughts and behaviour, as well as practise healthy positive thoughts and actions. It also uses stories and analogies as its narrative approach to exhibit and discuss positive and negative thoughts and behaviour that could impact the mental health of infertility patients. FELICIA (like the THP for safe motherhood), has been developed as non-specialist led intervention for infertility patients.

The intervention was delivered using a task shifting method. The counselling intervention is delegated to be delivered by nurses at the infertility clinics, thereby reducing the cost of delivering and increasing access for those who require the intervention. The package consists of 5 main modules: 1 compulsory module and 4 optional modules (refer to table 3.1). The optional modules were offered to patients as required by their individualised need at a point in time. The modules have been broken down into 10 counselling session. Of the 10 sessions, the patients picked six sessions based on their needs (Table 3.2). The sessions were delivered once a week over a six week period. Each session lasted no more than one hour. The counselling was delivered by nurses at the infertility clinics.

Research Objectives

To test the feasibility of FELICIA, using a pilot randomised control trial, on infertility patients with psychological morbidity at UCH Ibadan, Nigeria.

Research Question

Is FELICIA, a CBT based counselling intervention, feasible to be used as an intervention to reduce psychological morbidities associated with infertility amongst patients at University College Hospital, Ibadan?

Methodology

Eligible participants were recruited by randomisation into an external pilot trial of the intervention. Infertility clinic attendees with scores ≥3 on the GHQ12 were randomised into two groups- the intervention group (FELICIA) and the control group (usual care). The intervention had weekly counselling sessions over 6 weeks, using the FELICIA manual to deliver infertility counselling. The counselling sessions were delivered by the nurses at the infertility clinic who were trained by the researcher to deliver this intervention.

Inclusion Criteria

Consenting patients aged between 21 and 45 years attending the infertility outpatient clinics, the assisted reproduction clinics and other gynecological, andrology and nephrology clinics for infertility treatment, at UCH, Ibadan, were eligible for inclusion. These participants had been undergoing infertility treatment for at least 2 years, and had a GHQ 12 score of 3 or more, which was indicative of a psychological "caseness". The duration of treatment was determined during screening by asking participants how long they had been seeking infertility treatments. None of the participants were identified as having severe forms of anxiety and depression, using the mh-GAP guidelines (WHO, 2008). Patients were assessed during face-to-face meetings, before signing consent forms to participate in the research. During the recruitment process, it was stipulated that those who required urgent psychiatric assessment or treatment would be excluded from the study and directed to receive the required medical attention. Also patients who have previously been clinically diagnosed and treated for with a mental illness before diagnosis of infertility were excluded from the study.

Sample Size Calculation

The aim of a feasibility study is to determine the feasibility of doing a full randomized trial, not to determine efficacy of the intervention. The sample size is therefore usually time limited, rather than pre-determined. In this study the rate of case-ness from the cross-sectional study was not known, and neither was the recruitment rate from that cohort. It was decided therefore to

recruit 100 men and women in Ibadan to the cross-sectional study and then recruit as many of the cases as possible to the randomised trial. This resulted in a final sample size of 16.

A randomised trial of this size however does have some power to detect efficacy of the intervention (if the effect is large enough). For example, in a randomized controlled trial by study by Faramarzi et al (2008), 89 depressed infertile women were recruited and divided into three groups: cognitive behavior therapy (CBT), antidepressant therapy, and a control group (no intervention). Results showed successful treatment of depression in 50% of antidepressant therapy, 79.3% in CBT and 10% in control who had no intervention. Based on Faramarzi et al (2008) findings, determination of a sample size for this pilot randomized controlled trial at 80% power calculation shows that at least 14 participants (n=7 intervention group; n=7 control group), will be required, if we were to if we are to detect a 70% increase in participants who return to normal psychological scores.

Study parameters:	
Incidence, Intervention group (FELICIA)	79%
Incidence, Control group (Treatment as usual)	10%
Alpha	0.05
Beta	0.1
Power	0.8
Sample size, Intervention group (FELICIA)	7
Sample size, Control group (Treatment as usual)	7

With less optimistic levels of efficacy than this, the power of this sample size drops rapidly. For example, with an alpha of 0.05 and beta of 0.8, a sample size of 16 has only a 40% power to detect an increase in participants who return to normal scores from 10% to 50%.

Randomisation, Sequence Generation and Concealment

The participants who consented to participate in the research were randomised into 2 groups – the Intervention group (FELICIA) and the Control Group (Treatment as usual). The allocation was blinded using sequentially

numbered sealed opaque envelopes. The envelopes were prepared by an independent person, using the *Sealed Envelope* (www.sealedenvelope.com). All those carrying out the research had no knowledge of which group the contents of the envelopes indicated until it was opened.

Participants who were eligible and who had provided written consent to continue with the RCT were given a brown opaque sealed envelope at the group allocation stage. Depending on the content of the envelope, patients were randomised into either the intervention or control group.

Intervention Group (FELICIA)

Those in the intervention group (n=8) had 6 weekly counselling sessions using the FELICIA manual. On week 1 of the intervention, pre-intervention GHQ 12 scores were recorded for all participants in this group. In the same way, at the end of week 6 of the intervention, post intervention GHQ 12 scores were recorded. Pre and post GHQ 12 scores were analysed and outcomes compared.

Control Group (Treatment as Usual)

Participants (n=8) randomised into the control group did not receive any intervention. GHQ 12 scores were recorded at week one and week six, as for the intervention group. GHQ12 scores of participants in the control group were collected at the end of 6 weeks, either face to face and by telephone. Three of the eight participants had their GHQ12 scores collected by face-to-face interviews at UCH Ibadan, while the remaining 6-week GHQ12 scores were collected via telephone. Outcomes were recorded, analysed and compared with the intervention group.

Fidelity Measures for Intervention:

This FELICIA intervention is self-explanatory and required minimal training. In order to maintain the structure and standardised methods of intervention, each counselling session is done through a step by step guide detailed in the counselling manual to ensure FELICIA is delivered in the same way irrespective of the facilitators. Two nurses took part in the delivery of the intervention after successful training as explained in Chapter 4.

Clear guidelines were given to facilitate identification and referral of severe cases appropriately. Patients who are severely depressed or suicidal were to be referred immediately for specialist psychiatric assessment, although this was not required during this study. The research activities were under the supervision of the on-site supervisor, who is a consultant gynaecologist at UCH, Ibadan. In addition, nurses gave weekly reports to the researcher and the on-site supervisor, on activities pertaining to the intervention and the participants. All clarifications were addressed by the researcher and onsite supervisor to ensure the intervention was being carried out according the stipulated guidelines. The researcher had no contact with the participants during the 6 weeks counselling intervention.

Outcomes and Assessment Strategies

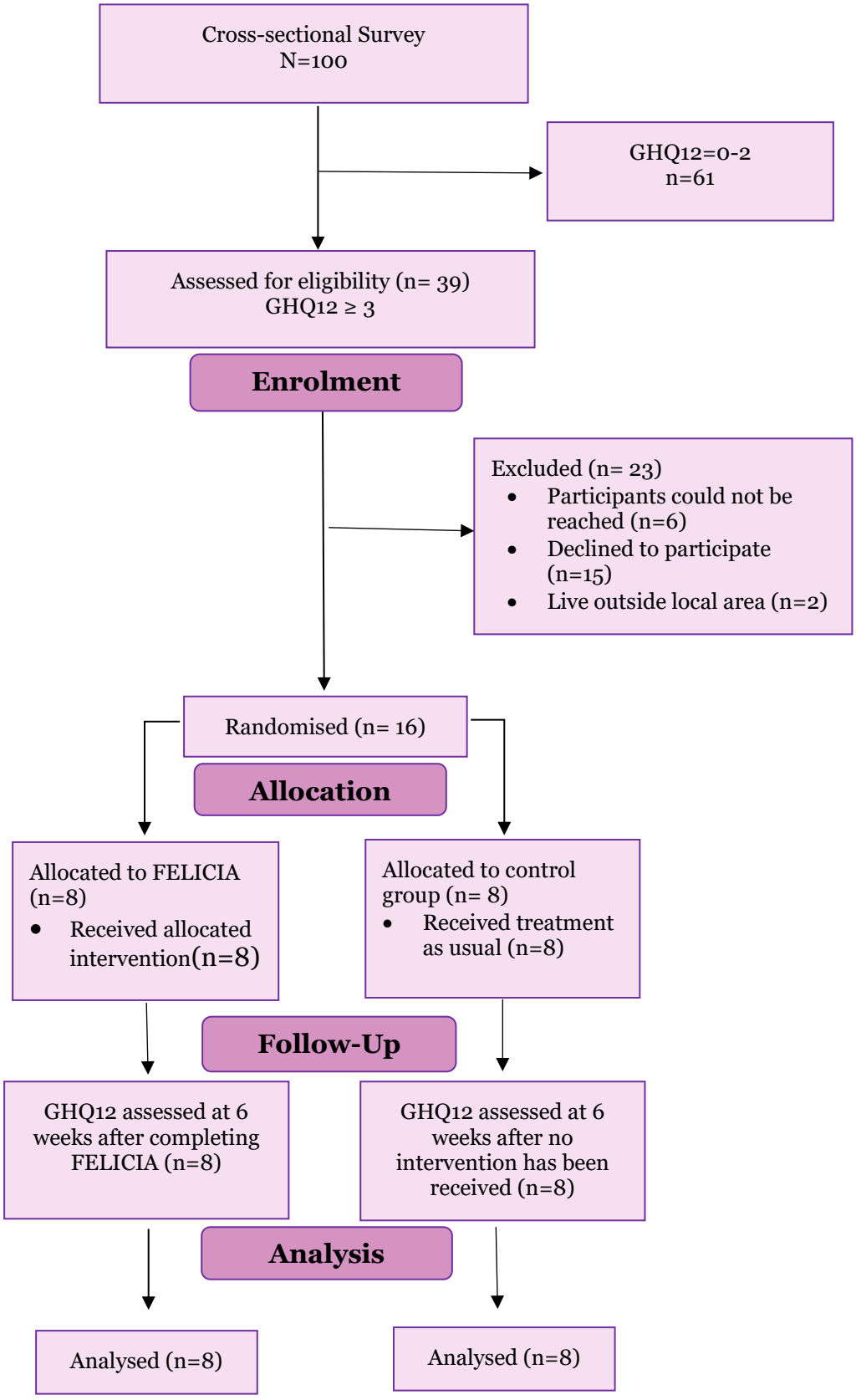
The presence or absence of a psychological morbidity was measured at the end of the intervention using the GHQ12 original scoring method (Goldberg et al, 1997). The primary outcome was patients having a GHQ12 score of 2 or less. This has been found to be consistently valid and reliable for detection of common psychiatric disorders in African, Asian and South American populations (Gelaye et al, 2015).

Self-reported GHQ12 questionnaires were scored using the original scale 0-0-1-1 (refer to table 4.1). Participants responding to statements were scored 0 or 1 for each of the 12 items, and added up. The lowest and the highest possible score using the original scale are 0 and 12, respectively. A GHQ12 score of 3 or more was indicative of psychological caseness according to validity studies in Nigeria, as shown in table 5.1 (Gureje & Obikoya, 1990; Abiodun, 1993; Abiodun, 1994).

Table 5.1: Recommended cut off points by validity studies within Nigerian populations (Goldberg et al, 1997)

Authors/Date	Setting	N	Threshold	Sensitivity (%)	Specificity (%)
Gureje &Obikoya,1990	Nigeria	214	0/1	67.0	74.0
Abiodun, 1993	Nigeria	272	3/4	83.7	79.8
Abiodun, 1994	Nigeria	263	2/3	88.7	83.3

Fig 5.1: FELICIA Feasibility study Flow Chart (CONSORT, 2010)



Statistical Methods

Analysis was carried out using statistically using the SPSS Statistics (Armonk, New York, version 22). Study participants were described by baseline characteristics. Outcomes of psychological caseness using the GHQ12 score in both intervention and control groups were compared using the chi-square test (or Fisher's exact test as appropriate). The relative risk of persistent psychological distress after 6 weeks of FELICIA was determined. The number of patients needed to be treated (NNT) for an additional patient to benefit from the FELICIA intervention was determined using Stats Direct (England, version 3.0)

Results

Participants were recruited from a survey that determined the prevalence of psychological morbidities associated with infertility amongst patients attending for infertility treatment (See chapter 4). Out of the 100 patients attending UCH Ibadan, 39 had GHQ12 results ≥3, indicating an ongoing psychological distress, and were approached to be recruited into the RCT. These were contacted by telephone, and 16 out of the 39 patients agreed to take part in the study. Fifteen patients declined to participate in the study. Two patients could not participate as they lived outside of the local area, therefore making it difficult to commit to attending for the weekly FELICIA sessions. All efforts to contact the remaining 6 participants for recruitment into the study proved abortive. Sixteen participants were recruited into the study. Participants were recruited over a period of 7 months from September 2017 to March 2018.

Descriptive data of the participants in the intervention and control groups are shown in table 5.2 and 5.4 below. All of the 16 participants were female, and aged between 21 and 45 years old. There were no drop-outs in this research as all those who consented to participate completed their 6 weeks observations. The two groups were balanced for age, past history, and cause and duration of infertility.

The intervention group consisted of 1 participant aged less than 25 years old, 3 participants aged were 26 to 30 years, 3 participants aged 31 to 35 years, and 1 participant whose age was above 35 years. There were 5 married women, 2 unmarried women and 1 woman who identified as separated or divorced. Only one out of 8 participants had an existing child. There was a history of domestic violence in 2 out of 8 participant in the intervention group. The highest and lowest GHQ12 score observed at week 1, before commencement of intervention were 10 and 4, respectively. The highest and lowest GHQ12 score observed 6 weeks post intervention were 3 and 0 respectively.

The intervention group consisted of no participants aged less than 25 years old, 2 participants were aged 26 to 20 years, 1 participant aged 31 to 35 years, and 5 participants whose age were above 35 years. There were 7 married women, 1 unmarried woman; none of the participants in this group identified as separated or divorced. Only one out of 8 participants had an existing child. In this group, 4 out of 8 participants had a history of domestic violence in the home. The highest and lowest GHQ12 score observed in the control group at week 1 were 7 and 3, respectively. The highest and lowest GHQ12 score observed after 6 weeks of allocation to control group were 7 and 1 respectively.

Table 5.2: Descriptive statistics of comparing participants in the FELICIA and Control groups.

Parameters	FELICIA	CONTROL
Age group (years)		
≤25	1 (12.5%)	0 (0.0%)
26-30	3 (37.5%)	2 (25.0%)
31-35	3 (37.5%)	2 (25.0%)
>35	1 (12.5%)	4 (50.0%)
Marital Status		
Married	5 (62.5%)	7 (87.5%)
Separated or Divorced	1 (12.5%)	0 (0.0%)
Unmarried	2 (25.0%)	1 (12.5%)
Nulliparous	7 (87.5%)	7 (87.5%)
Pre-intervention Mean Baseline GHQ (SD)	6.63 (2.2)	5.38 (1.4)
History of Domestic Violence	2 (25%)	4 (50%)

The results suggest that the intervention may be effective in reducing psychological distress associated with infertility, when compared to the control group which had no intervention (Table 5.3; Fig 5.2). At the end of the study in the intervention group, 7 out of 8 participants had normal GHQ12 scores. In contrast, the scores normalised in only 1 out of 8 participants in the control group (Table 5.4; X^2 = 9.0; df=1; p value = 0.01). The relative risk calculations indicated that the risk of not having GHQ12 score of less than 3, after 6 weeks of the FELICIA programme is 0.143 (95% CI 0.023 - 0.91, p value= 0.04), when compared with the control group. The estimated number of patients needing to be treated (NNT), using FELICIA, for one additional patient to benefit is 1.33 patients (95% CI= 0.93 - 2.35 benefit).

Table 5.3: Compared outcomes of psychological distress between the FELICIA and control groups after 6 weeks.

	FELICIA (n=8)	CONTROL (n=8)	Statistics
Mean GHQ score (SD) at week 1	6.63 (2.2)	5.38 (1.4)	p = 0.01* RR= 0.143 (p=0.04)+ (95% CI 0.023 – 0.91).
Mean GHQ score (SD) at week 6	1.25 (1.1)	5.13 (1.8)	
Improved GHQ score after 6 weeks	7 (87.5%)	1(12.5%)	

*Fischer's exact test; +Students t-test

Table 5.4: Demographic distribution of participants in the FELICIA and control groups.

Participant No	Age Group	Marital Status	No of Children	Pre FELICIA GHQ12	History of DV
FELICIA GROUP					
1F	31-35	Married	0	10	Y
2F	26-30	Married	0	5	N
3F	26-30	Married	1	5	N
4F	31-35	Married	0	9	N
5F	>35	Separated/Divorced	0	5	N
6F	≤25	Unmarried	0	7	N
7F	31-35	Unmarried	0	4	N
8F	26-30	Married	0	8	Y
CONTROL GROUP					
1C	>35	Married	0	3	N
2C	>35	Married	0	7	Y
3C	>35	Married	0	4	Y
4C	26-30	Married	0	7	N
5C	31-35	Married	0	5	Y
6C	26-30	Married	0	6	N
7C	>35	Unmarried	1	5	N
8C	>35	Married	0	6	Y

GHQ 12 Analysis

According to the validity study by Gelaye et al (2015), the different items on the GHQ12 are indicative of anxiety, depression and social dysfunction. Items 1, 2, 3, 4, 5 and 6 suggest anxiety and depression, while items 7, 8, 9, 10, 11, and 12 indicate social dysfunction and depression (Gelaye et al, 2015). Based on this evidence, it shows that while individual anxiety, depression and social dysfunction were improved in the FELICIA (intervention) group, these problems persisted in the control group who were treated as usual (Fig 5.2; 5.3; 5.4). There were significant differential improvements observed in the intervention group when compared to the control group.

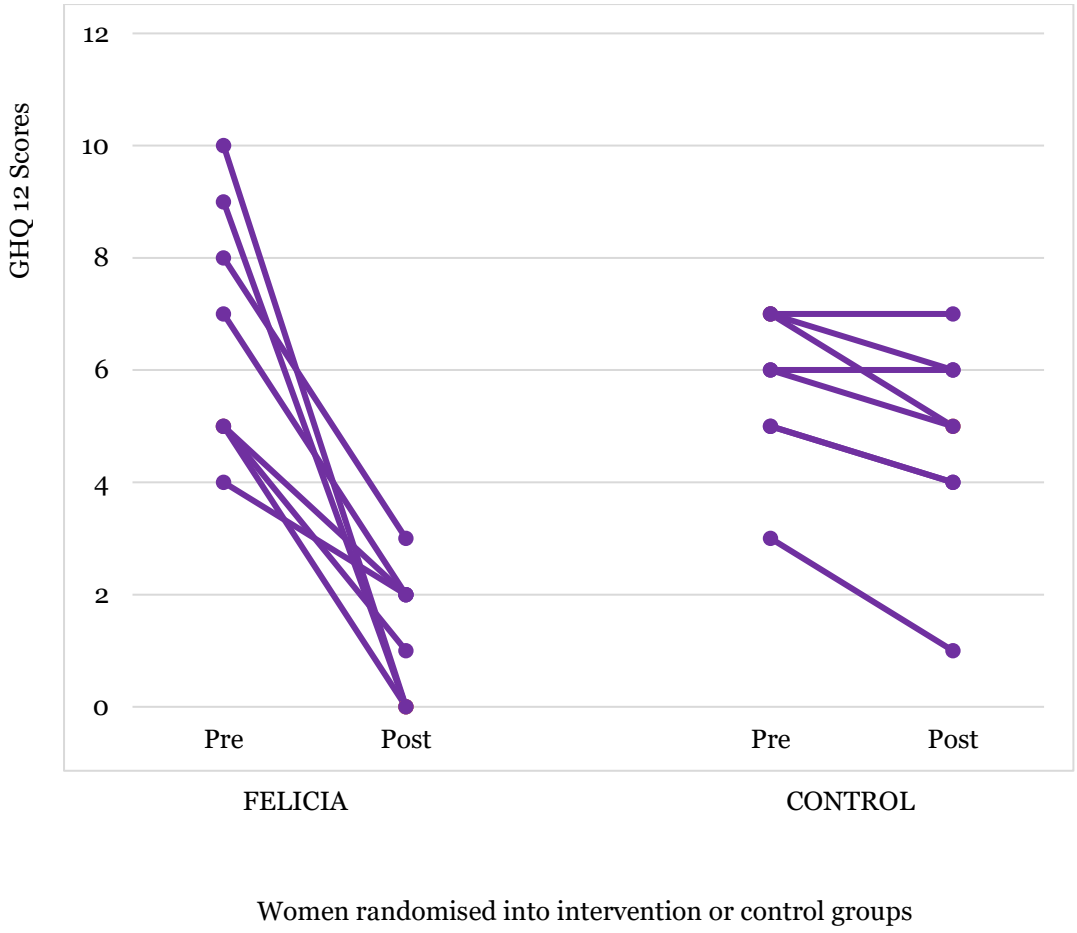
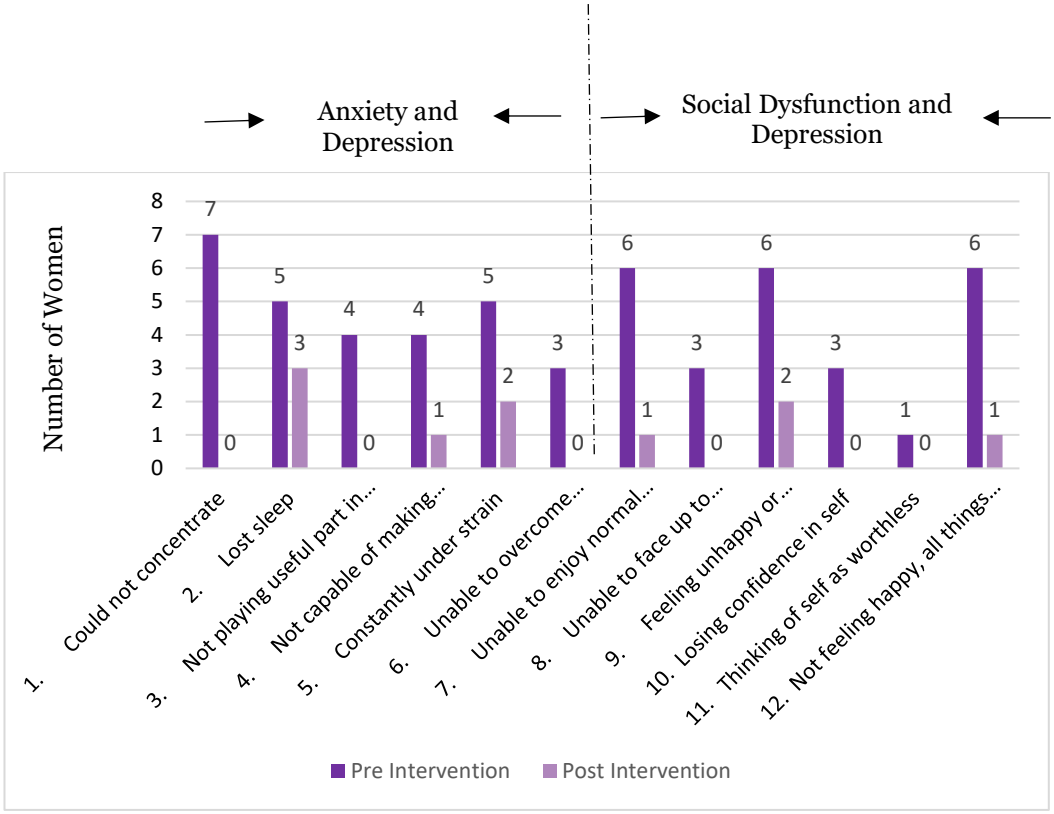


Fig 5.2: Comparison of GHQ12 scores of participants at pre and post interventions stages, in the intervention and control groups.

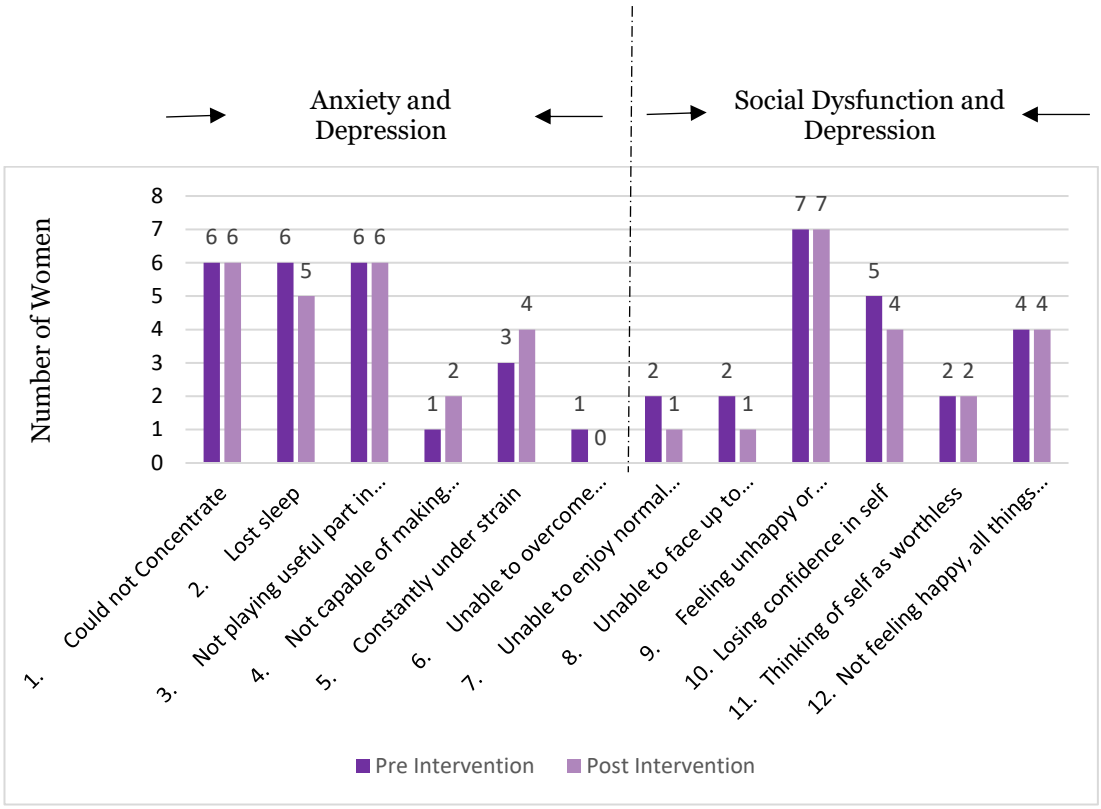
In the intervention group (Fig 5.3), marked improvements was seen in participant responses to all 12 questionnaire items after the 6 week intervention, shown by a reduction in the number of patients who responded positive to the questions asked. The greatest improvement was seen in item 1, where 'loss of concentration' reduced from 7 women to 0. 'Loss of sleep' (item 2) showed the least improvement as it was observed in 5 women before, and 3 women after the intervention.



GHQ12 questionnaire items

Fig 5.3: Improvement in of the state of psychological wellbeing according to GHQ 12 items in intervention group

In the control group (Fig 5.4), where had no intervention was received, there were no changes observed in the no participants responses to the GHQ12 items 1, 3, 9, 11 and 12 ('loss of concentration', 'not playing a useful part in things', 'felling unhappy or depressed' and 'feeling worthless'). The number of women responding positively to items 4 and 5 ('feeling constantly under strain' and 'inability to make decision') increased. There were slight improvements observed in the remaining items. 2, 6, 7, 8, and 10.



GHQ12 questionnaire items

Fig 5.4: Improvement in of the state of psychological wellbeing according to GHQ 12 items in the control group

Pilot study parameters:

This feasibility study has been carried out to test the intervention and assess important factors in the design of the main study (Arain et al, 2010; Lancaster et al, 2004).

<u>Relative risk calculation, standard deviation and sample size calculation of main RCT</u>

The relative risk calculation and standard deviation of the outcome measure shows a strong likelihood of a reduced risk of psychological distress persisting after exposure to 6 weeks of FELICIA (RR=0.143; 95% CI= 0.023 - 0.91, p value= 0.04), which will also be beneficial in calculating the sample size for a full randomised controlled trial. The required sample size for a larger RCT was determined at 90% power calculation. It shows that at least 84

participants (n=42 intervention group; n= 42 control group), will be required for the full RCT, if we were to if we are to detect a conservative 30% increase in participants who return to normal psychological scores.

Table 5.5: Determined the minimum number of participants required for full RCT.

Study Parameters	
Resolution of symptoms in FELICIA group	42.5%
Resolution of symptoms in control group	12.5%
Alpha	0.05
Beta	0.1
Power	0.9
Sample size, Intervention group (FELICIA)	42
Sample size, Control group (Treatment as usual)	42

Adherence, compliance and follow up rates

Although recruitment rates show that 16 out of 39 (41%) of eligible patients consented to take part in the feasibility study, those who participated showed a willingness to be randomised into either the intervention or control groups. In the intervention group, all participants were compliant to the protocol of the intervention. Even though the intervention was designed to take place every week for 6 weeks. Allowances were made for logistic delays in completing the intervention, and consequently a rescheduling in the post intervention GHQ12 evaluation. Five out of eight (62.5%) participants completed their intervention within 6 weeks, 2 participants (25%) needed an additional 1 week to complete because they had missed one session, and the last participant (12.5%) completed in 8 weeks for the same reasons. In the control group, all participants (100%) were available at the end of 6 weeks for their GHQ12 evaluation.

The follow up rate was 100%. All participants in the intervention and control groups were available to be evaluated after completion of intervention (or no intervention in the control groups).

Discussion:

Effectiveness of FELICIA as an intervention

Overall, the results of this feasibility study suggest that FELICIA has the potential to reduce the psychological morbidities associated with infertility. The findings also provide parameters and factors to be considered when designing a protocol to evaluate the relevant outcome; which is a reduction in anxiety, depression and psychological morbidities as a result of infertility (Lancaster et al, 2004; Arain et al, 2010; Eldridge et al, 2016). According to Eldridge et al (2016), feasibility studies are conducted in preparation of randomised controlled trials and there are 3 study types categorised under feasibility studies. These are randomised pilot studies, non-randomised pilot studies, and feasibility studies that are not pilot studies (Eldridge et al, 2016).

Using a pilot randomised trial as a method of carrying out a feasibility study, we tested FELICIA for its effectiveness in reducing psychological distress associated with infertility and also evaluated other parameters that will influence the development of a research protocol for a main study with the primary outcome of reducing, anxiety, depression and social dysfunction as a result of infertility (Lancaster et al, 2004; Arain et al, 2010; Eldridge et al, 2016). We found that the women who participated in the intervention had significantly improved psychological health and wellbeing when compared to the other group that had no intervention, irrespective of demographic differences. This result is in keeping with the meta-analysis conducted by De Liz et al (2005), which compared the efficacy of individual, couple or group therapies on negative emotional symptoms due to infertility, and the possibility of increasing pregnancy rates. The findings showed that individual, couple, or group psychotherapy caused a reduction anxiety and depression disorders as a result of infertility, that was sustained over 6 months (de Liz et al, 2005).

Psychotherapy for infertility patients has been shown to be effective for holistic management of infertility. However, in many African communities, there are limited human and financial resources to provide skilled psychotherapy for infertility patients. More so, there is the question of affordability for patients to access these services, even if they were readily

available. For many infertility patients, the cost of medical treatments and assisted reproductive techniques is too high for them to afford additional skilled psychotherapy. This shows a need for a low cost effective psychological intervention that can reduce the infertility-induced psychological distress, such as FELICIA. The intervention also utilises readily available staff, the FELICIA trained nurses and health workers, to deliver the intervention.

Adherence and compliance to intervention

The high compliance and follow up rates shows that the intervention is acceptable to the participants, therefore the target population. The GHQ12 questionnaire as a tool to measure outcome was acceptable and favourable for the participants. The GHQ12 questionnaire, being a short tool that requires little time to complete, contributed to the compliance of participants as it was not burdensome. Regarding compliance to the intervention itself, the perception of the participants who completed the intervention was evaluated using a qualitative research via semi-structured interviews. The details of the findings are elaborated in Chapter 6.

Challenges and Limitations

Recruitment

A major challenge of the study was the recruitment of participants. The recruitment rate at the start of the study was 41%. This was due to a number of factors such as the perceived convenience of participating in a novel intervention, patients having to travel far distances to receive treatment at UCH, Ibadan, and, the difficulty in contacting participants who had been found to be eligible for the study. The researcher had to rely on telephone numbers provided by the participants the only means of contact, and if they could not be reached, they were a loss to recruitment. For many other participants, taking part in "another unfamiliar intervention" in addition to many treatments and clinic appointments, was too overwhelming and they lacked the time or the emotional capacity to consider creating space for another "therapy". Furthermore, UCH, Ibadan is a well-regarded heath institution that attracts patients from all over the country. For most patient

who did not live locally, it would not be possible to travel every week to receive counselling, if randomised into the intervention group. Those who took part in the study were the willing ones who were most likely to be receptive to the intervention. If FELICIA was made available locally to those who need infertility counselling, lack of recruitment would have been less of an issue.

Validating of the implementation of FELICIA

In the intervention group, FELICIA was designed to be carried out by nurses who had been trained to deliver the intervention. Although FELICIA uses a step by step task-based approach, there is the human factor that may influence discussions, explanations and meanings. This introduces more variability in the outcomes due to the subjectivity of the intervention, which can influence the ability and efficiency of the health worker to deliver the intervention. A good "counsellor" is more likely deliver positive outcomes with their clients, and vice versa.

Bias

The measure for psychological distress pre and post intervention in both groups were the use of a self-reported questionnaire, the GHQ12. This introduced the possibility of self-reporting bias. Self-reporting bias could happen in 2 ways in this study. First, there is the recall bias, due to participants to recollecting their true feelings which may have been supressed as a coping strategy. Secondly, there is the chance of a social desirability bias as a result of participants wishing to impress or appease the researcher efforts, by responding to the GHQ12 questions in a way that they perceive to be a favourable or acceptable outcome. This was overcome by during the participant recruitment when information about the research was being shared. Participants were encouraged to be honest about their responses to the best of their ability because their responses, or lack of it, would have no effect on the statutory rights as patients seeking infertility care. They were also advised that their honest responses help determine if the intervention is indeed effective, in addition to providing information to improve upon the intervention for future use.

Lack of male representation

Although the study was designed to recruit men and women, men were grossly unrepresented in this study. This was due to a larger population of women seen in the infertility clinic. Only 10% of the eligible participants were men, and none wanted to take part in the intervention. It would be interesting to know if FELICIA would produce similar outcomes in reducing psychological distress in men who have infertility issues, as well as assessing the acceptability of the intervention amongst the male population.

Possible bias due to lack of attentional controls

Attentional bias is the tendency for participant perceptions to be affected or influenced by their recurring thoughts, leading to inability to consider alternative thoughts or possibilities. Muris et al (1998) describes this as a hyper-attention to threatening material. Patients with anxiety and/or depression show attentional bias towards negative stimuli, with a greater vigilance for threat seen in the anxious groups (Rinck and Becker, 2005). Research also shows that anxious patients have difficulty disengaging from threat stimuli, often leading to delayed or no disengagement, with a facilitated attention for threat (Cisler & Koster, 2010)

Amongst infertility patients in Nigeria, there is a higher exposure to stress and adversity, and therefore are more sensitised to notice negative cues or stigmatising behaviour, as well as ignoring positive cues, when compared with the general public (unexposed group). Patients feeling marginalised may therefore be unable to see things as they are and assume that unrelated cues are negative and directed towards them due to childlessness or their inability to have a desired pregnancy. In the same way, after exposure an intervention such as FELICIA which promotes positive outlook to circumstances, participants may also become unrealistically biased towards positive stimuli. Therefore, when dealing with family and friends or making decisions, they are more likely to be biased towards positive cues, with increase social engagement and positive outlook and outcomes as seen in the results of the intervention group of this research. The ability of patients to see the good with the bad, purely as they are, provides a balanced approach to making the right decision regarding their infertility treatment choices.

In this study, the attentional control in the attentional bias was not measured. The attentional control is a measure of the ability to disengage from threatening stimuli. This means that a person with poor attentional control demonstrates poorer regulation of attention allocation, and a greater difficulty disengaging from negative cues, and vice versa. Amongst infertility patients, their attentional control could affect their response to negative behaviour from the community, as well as their response to the intervention. These could present as confounding factors, which has an effect on the outcomes of the study.

Future Directions

Further research is needed to test FELICIA, in the short and long term, as an intervention to reduce psychological distress related to infertility. This research will help determine the efficacy of the intervention, using a larger randomised controlled trial, amongst a male and female population. Furthermore, research has shown that psychological distress affects the neuro-endocrinology pathways, which may lead to supressed fertility (Cwikel et al, 2004). Further research is required to assess the effect of FELICIA on pregnancy rates among infertile women using randomised controlled trial method. Also, health economics analysis is required to determine healthcare and social cost-effectiveness of FELICIA, as an intervention for infertility-related stress management.

Chapter 6:
A Qualitative study exploring the perception of infertility patients to the FELICIA programme, in a Nigerian setting

Introduction:

Studies have shown that in spite of the need for infertility counselling, patients preferred to talk to their spouse, family and friends for counselling during distress, instead of formal counselling and support services. Reasons given included the preference to use familiar sources for support, a lack of awareness about available resources, as well as the cost implications of taking up such resources (Joy and McCrystal, 2015). The principal reasons preventing patients from counselling uptake have varied, with less distressed patients using their existing resources, and more distressed patients failing to initiate contact with the counselling service because of practical concerns such as not knowing how to do so and cost implications.

Evidence shows that an average of 20% (18-21%) of infertility patients in Europe participate in infertility counselling as part of their management; higher uptake was reported in those with higher level of education and socio economic classes (Boivin et al, 1991; Seligman 1995; Wischmann et al 2009). According to Emery (2003), psychosocial infertility counselling is essential for fertility treatment, and when the set objectives are clear from the onset, acceptance of counselling interventions increase significantly. Counselling impacts positive psychological and social health, thereby contributing to reducing dropout rates in treatment (Allan and Roudsari, 2011).

Studies show that cognitive behaviour therapy and other psychotherapeutic methods, have been successful in treating depression and other mental health conditions globally (Churchill et al, 2001; Patel et al, 2007; Rojas et al, 2007). However, in middle and low income countries, the mental health sectors has a scarcity of mental health professionals to deliver these

interventions to deprived communities (Saxena et al, 2007; Rahman et al, 2008).

FELICIA, an infertility counselling intervention was adapted to be delivered by conventional health workers without previous training in mental health (FELICIA, 2018). This was developed in response to a demand for psychological support for infertility patients demonstrated by the findings in literature review in Chapter 2, as well as the result of the cross-sectional study in Chapter 4. FELICIA originated as an intervention to manage the psychological morbidities associated with infertility, especially in resource-poor settings. Details of its development were explained in detail in Chapter 2. The results of the cross-sectional study revealed that 43% (N=224) of infertility patients surveyed had some psychological morbidity according to the GHQ12 scoring. As a result, 16 participants whose GHQ 12 showed psychological caseness were taken through a pilot randomised control trial (RCT), with 8 in the intervention and 8 in the control group. The results of the pilot RCT showed the intervention to be effective in reducing psychological morbidities identified in the participants, with a marked reduction in the GHQ12 scores of those who took part in the intervention, versus the control group. A qualitative study was carried out to explore the patient perspective of the identified benefits, and challenges, of the 6 week intervention. This chapter describes a qualitative research exploring the patient perspectives of the FELICIA programme.

Research Objective

To understand patients' perspectives of the potential benefits of the FELICIA intervention, 6 weeks post intervention.

Research Question

What are the perceptions of patients about the benefits, and problems of 6 weeks of CBT based counselling (FELICIA) received at the infertility clinic at University College Hospital, Ibadan?

Methodology:

Qualitative research using semi structured interviews was chosen as the best method to determine participants' perspectives on the benefits of the intervention. It was also a secondary outcome of the pilot RCT described in Chapter 5. Qualitative research was chosen as the method with which to approach the research questions due to the importance of understanding the meanings of expressions and experiences in the participants' own words based on the context in which the events are occurring. According to Henwood (1996), qualitative methods address the concerns of inappropriately 'fixing meanings' to quantitative results, which are variable depending on the context of use.

Epistemology and Theoretical assumptions

In research, social constructivism is typically seen as an approach to qualitative research (Creswell, 2009). The social constructivist holds the assumption that the world is complex and that people develop meanings and ideas that are subjective, varied and multiple based on human experience and the context in which they find themselves. The researcher searches for these varied meanings and complexities towards a certain event or phenomenon rather than focus on a narrow idea or perspective. The goal of qualitative research then is to rely on the participants' perspectives and interpretation of the subject of study (Creswell, 2009).

Mental health is a state of the mind, even though it may stem from a biological or pathological aetiology. The way people react or cope with certain life events such as infertility differ widely based on several other factors that are complex and interlocked in an individual's day to day activities, expectations, responsibilities, weakness and strengths. It is also influenced by our awareness of the issue at hand (if we consider it to be a problem), and how willing we are to seek help should the occasion arise. In the same way, the response to an intervention to combat these psychological morbidities associated with infertility such as FELICIA would differ widely in terms of its efficacy for the patient. With this in mind, qualitative research provides the

approach needed to adequately explore the patient perspectives about the effectiveness and benefits of FELICIA.

Semi-Structured Interviews

The method of data collection that was used is semi structured interviews. This method enables the researcher to explore the research question in depth and also allows the participants to express their views in their own words, enabling a better understanding of their perspectives on the intervention. Similarly, the method enables the researcher to have a better understanding, by requesting clarifications and meanings within discussions, in order to gain a comprehensive understanding of what the participant is meaning to say. Due to the sensitivity that accompanies the discussion of infertility and psychological and/or mental health, it accommodates a one-on-one approach that ensures confidentiality and privacy as well as gaining the trust of the participants in that the discussion that was kept anonymous through the entire process.

The option of a focus group discussion was considered during the research planning. The benefits would be that participants could gain and discuss other ideas and views from other participants in the room, thereby increasing the wealth of data. However, it was felt that in focus group discussions, where other participants will be present, some participants may be reluctant to express their personal views or discuss their experiences of their infertility journey in the presence of other people that they barely knew. A decision was therefore reached to restrict the data collection to personal interviews only.

The sampling was convenient. Participants who completed 6 weeks of FELICIA intervention and gave consent to continue with the qualitative aspect of the research project were recruited to participate. The participants were familiarised with the research plan through the participant information sheets which detailed all aspects of the research project and its methodology (see index). Interested participants were asked to arrange a suitable date and time for the interview to take place.

The FELICIA intervention was tested among the participants prior to commencement of the interviews. The participant for the pilot study was a female infertility patient, identified as having psychological morbidity due to infertility during the cross-sectional study in Chapter 4. She was offered the intervention external to the randomised trial, and was aware that this was the first test of the intervention. She completed the FELICIA programme, facilitated by the researcher, and at the end of 6 weeks was asked the about her perception of FELICIA, using one to-one interviews. The data collected at this stage was not included in the results for this study. Firstly, because it took place prior to recruitment and randomisation in Chapter 5. Secondly, the participant's FELICIA intervention was facilitated by the researcher and not the nurses. This allowed the researcher to test the interview questions, to determine if they were understandable, reliable, and to ensure that the research aims of the study were being met.

After the initial test, the interview questions were modified slightly to improve the quality of the questions so as to draw out useful information from participants. Subsequently, a final set of questions were derived for the semi - structured interviews (Table 6.1).

Table 6.1: List of Semi-structured Interview Questions

Question No	Questions asked.
1	What do you think about the FELICIA counselling programme overall? Can you give practical examples about your experiences?
2	Did you find this counselling programme useful to you? If yes, why and how? (Please give examples) If No, why/why not? (Please give examples)
3	Did you feel empowered after participating in the intervention? Why or why not? (Please give practical examples of your experiences)
4	If you could change anything about this programme method, what would that (or these) be? Why would you prefer to see these changes?
5	Would you recommend the FELICIA programme to other people in the same situation as yourself? Why/Why not?

As a result, the semi structured interview consisted of 5 questions. Questions 1 explored participants' understanding of FELICIA as an intervention and its core principles. It explores the understanding of the 3 steps of Thinking Healthy as the core principles of FELICIA. Questions 2 explores the patients' perspectives on the benefits of FELICIA after 6 weeks of participation. Question 3 explores the feeling of empowerment after participation, especially how they have been able to apply the core principles of the intervention to tackle the sources of psychological morbidities, thereby gaining a sense of empowerment in doing so. Question 4 and 5 explores the potential challenges of participating in this intervention and the willingness to recommend the intervention to other infertility patients who might benefit from such interventions. All 5 questions explore perceptions, attitudes and beliefs in relation FELICIA, to an intervention developed to reduce psychological morbidities of infertility. Issues explored included the role that culture, traditional and religious beliefs as well as how family and friend relationships are affected and/or improved after 6 weeks on intervention. It explores how participants' have been able to combat the role of stigma on their mental health as well as dealing with all potential sources of discrimination and abuse as a result of infertility.

Justification for empowerment questions

Empowerment involves a process of giving power to an otherwise marginalised person or group or to gain control over one's own life from a tradition, culture or belief that causes a surrender of power or marginalisation (Rappaport, 1981; Sadan, 1997; Zimmerman, 2000; Moran et al, 2017). Empowerment focuses on strengths, viewing individuals as having competencies and independence, yet requiring opportunities and resources in the external environment in order to optimise those potential opportunities by providing the needed resources and collaborating with relevant professionals (Moran et al, 2017).

One of the guiding principles of the development of the FELICIA programme is empowerment which aims to encourage the participants to engage in the discussions with the health care team during counselling sessions. It also gives people dealing with infertility to take active ownership

of their thoughts, as well as a platform to begin challenging negative beliefs and perceptions, thereby fostering new positive ways of thinking about the problem infertility physically, socially and psychologically. The changes potentially lead to positive outcomes which are empowering.

In order to assess if this aim has been achieved, it is important to ask participants about their feelings of empowerment by giving practical examples of how they have been able to perceive this.

Participant Recruitment and Sample Size

Participants recruited for the study were infertility patients who had completed 6 weeks of infertility intervention. The participants who took part in the study were people of reproductive age group from all walks of life, who were attending for infertility treatment at the University College Hospital in Ibadan, Nigeria. The age group of the participants ranged from 26 to 45 years old. All participants were able to communicate verbally and clearly in English language, hence there were no requirements for translations.

Research Setting

Participants were interviewed at various prearranged locations and time. Interviews were done face to face and by telephone. All respondents participated in their interviews alone. This enabled the researcher and the participant to discuss without interruptions or distractions from other outside of the conversation. It also allowed the participants to discuss their perceptions in confidence without fear of judgement by other listening parties. The participants were also able to re-live their experiences of dealing and coping with infertility, by comparing their attitudes and behaviour before and after the intervention. Participants were able to use the principles of the intervention to discuss lifestyle and behaviour change, by relating it to events that have happened in the past and how they intend to respond to similar events in the future.

Data Collection

The semi structured interviews were recorded using a voice recorder. All the information was kept entirely anonymous and participants were

numbered 1-7 where such notes were written down; identifiable data such as names were not included in the notes so as to maintain privacy. The data from the voice recorder was stored on a password protected computer. The informed consent forms were also kept under lock and key at all times.

It is important to note that the participant was fully informed of the events that will take place and what was to be expected. All the information was included in the participant information sheets that were given to participants, by the research, to read before agreeing to take part in the study.

Translation and Transcribing

The interviews were audio recorded on a digital voice recorder. The recordings were downloaded and stored on a password protected computer and then transcribed verbatim by the researcher. The stored recording will be held by the researcher until the dissertation is complete after which it will be destroyed.

The transcribed data was used by the researcher to illustrate results and findings as well as to develop themes and headings. All data was collected, stored and used in accordance to the UK Data Protection Act (1998). During data collection, participants responded in English language but used certain words or phrases within sentences in the local (Yoruba) language to buttress their point and meanings. This was translated into English language and the meaning was fully understood because the interviewer is of the same ethnicity and communicated effectively in Yoruba Language. However, all participants could communicate clearly and verbally in English language, the use of phrases in the local language helped them to communicate their experiences in a way that the interviewer could completely grasp the context of what was being described. For example:

> *"... sometimes they might say "See how this one is dressed." As if I am overdressed or something...I say "This is nothing, bigger things are coming". **Mo şęşę bęrę** [translation from Yoruba to English language: I only just started]. I say by the time I come out with this or that, they'll know I mean business. You know I just show them I am not affected by their comments."* (P5)

Data Analysis

The data from participants' responses were transcribed and manually coded. The interviews were collected and transcribed personally by the same person, the researcher. During the research analysis, transcribed data were checked for accuracy by cross-checking the transcription with the audiotape recording twice. The transcribed data were read with scrutiny and careful consideration in order to extract emerging themes and their relationships. The process involved repeatedly listening to the voice recording and reading of notes allowing the researcher to become fully immersed in the data.

The emerging themes were organised by topic into main themes, categories and sub-categories; this was based upon participants' responses within the identified themes. At the end of each interview, the researcher made notes of emerging topics of each participant during the research process. This made the development of themes collectively at the end of the interview process and the analysis stage more organised and manageable (Bowling, 2002). Also, the observation notes made during each interview served as a useful reminder of the context of participant responses; this enabled an in-depth understanding and added meaning to what participant was saying.

The researcher employed a thematic framework analysis which involved deriving themes or concepts under which data could be categorised, labelled and compared (Ritchie and Lewis, 2003). The thematic framework is used to classify and organise data according to key themes, concepts and emergent categories. This framework has five key stages (Richie and Lewis, 2003):

1. **Familiarisation**

   The researcher was personally responsible for recording, reading and transcribing the data and has become fully immersed in the data collection and analysis process.

2. **Identification of a thematic framework**

   Through familiarisation, the researcher is able to use common phrases and description that lead to emergent themes during the data

collection process. These themes are then organised into main themes, categories and subcategories.

3. Indexing

This involves labelling the key issues that have been derived and developed within the data collected.

4. Charting:

By developing a series of thematic charts, the researcher allows patterns of emergent themes to be explored and reviewed.

5. Mapping and Interpretation

Mapping and interpretation involves a process whereby the researcher examines and is able to interpret the data as a whole. It allows for comparing perceptions and experiences and determining relationships and patterns between within emergent themes and to derive explanation regarding each theme and in relation to other themes or issues in the research.

The researcher familiarised herself with the data by personally collecting, recording and analysing the data. The data was also repeatedly reviewed and reread in order to gain a full understanding and to reduce the possibility of missing out in meaning and description of experiences testified by participants. The data were separated into main themes categories and subcategories, and the process was on-going and repeated several times. It is also worthy to note that because of the subjective nature of the research design on the part of both the participant and the researcher, the researcher made sure to note emerging themes from each data set from each participant after each interview. This was to minimise the possibility of leaving out important information, it also made the analysis process easier and more organised.

Analytical rigour was also demonstrated during the data analysis by thorough deliberation amongst the research and supervision teams to identify and compare emerging themes and theories. Regular monthly supervisory and analysis discussion meetings were arranged to compare and contrast the identified concepts and categories derived from data analysis, thereby deliberating on the relationships and ideologies. This involved regular

consultations with the 2 university of Liverpool supervisor, as well as the on-site supervisor at UCH, Ibadan, where data was being collected. The regular thorough deliberations, considerations and comparisons led to the deduction of the final analysis of findings discussed in the results section of this chapter.

The transcribed data were each labelled "Participant 1" up to "Participant 7" (P1-P7) and derived themes of each participant were labelled in the same respect. At the end of the interviews all the gathered emergent themes and topics were collated and organised into a more robust and definitive themes, categories and subcategories as documented in the results section.

Credibility

The interview discussions were recorded on audiotapes and transferred unto an electronic source which is available for confirmation.

Ethical considerations:

Ethical Approval

Before the start of recruitment, full ethical approval was sought and granted by the University of Ibadan/ University College Ibadan (UI/UCH) Ethics Committee as well as University of Liverpool Ethics committee (see appendix). It was required as the research involved human participants (Bowling, 2002).

Consent and Consent forms

Informed consent was obtained to permit the researcher to collect data through the interview process, to store data and to use the data from participants, for the purpose of this research only. Prior to requesting signed consent forms, the participants were given the participant information sheets to read. As a requirement of the UI/UCH ethics committee, the participant information sheets and the consent forms were translated into the local language (Yoruba language), in case it was needed.

Results:

Descriptive Statistics

Descriptive data of the participants of this research are shown in table 6.2 below. Verbatim quotes were marked with codes to preserve anonymity. Participants were labelled "P" with their corresponding number. For example, participant 1 was labelled P1, and participant 2 labelled P2, etcetera. All of the 8 female participants who completed the FELICIA intervention were eligible to participate in the one to one interview (see chapter 5). The one FELICIA study participant who dropped out did so before the interview process. Unfortunately, all efforts to contact her proved abortive; her telephone number could not be reached. Although she has been excluded from the qualitative research analysis, her descriptive data is worthy of note as she identified as currently experiencing domestic violence by her spouse. She was also the only participant to display a post-intervention GHQ12 score indicative of an ongoing psychological distress. Her views on the impact of the FELICIA intervention to her coping abilities for infertility related psychological distress remain unknown. Whether she might have benefitted from further interventions tailored to alleviate her problem of domestic violence is a question still unanswered.

Table 6.2: Descriptive Statistics of Eligible participant for one to one interviews of FELICIA participants, post intervention.

Participant	Sex	Age Group	Marital Status	No of Children	Method of Interview	History of DV
P1	F	31-35	Married	0	Face to face	Y
P2	F	26-30	Married	0	Face to face	N
P3	F	26-30	Married	1	Face to face	N
P4	F	31-35	Married	0	Telephone	N
P5	F	>35	Separated/ Divorced	0	Face to face	N
P6	F	≤25	Unmarried	0	Telephone	N
P7	F	31-35	Unmarried	0	Telephone	N

All participants were of child bearing age (Table 6.1). Four out of the seven of the women were married. All participants had GHQ12 score of 3 or more before participating in the FELICIA intervention, but all 7 participants had reduced their GHQ12 scores below the threshold for psychological distress, at the time of the interview.

Domestic violence was self-reported in one participant She discussed how she was able to overcome this abuse by people in the community, not allowing it to affect her and learning not to attach importance to what was being said by separating personal opinions from facts. P1 narrated how she was being commended for being on time and efficient in her role an usher in the church by the group leader. Nonetheless her commendation was met with disdain from the other women within the group.

> *"…They were trying to say they were not able to meet up with the time because they had kids that they were caring for at home and I was able to meet up because I haven't got any kids to cater for. I just looked at it as 'normal' (irrelevant) talk… as in everyone is entitled to their opinion. I decided I was not going to allow their negative comments to weigh me down whereby I will start thinking about what they said or what it could have meant…"* (P1)

Themes and sub categories

Four main themes emerged from this research analysis and they include:

1. Perceived benefits
    a) Improved coping strategies
    b) The trickle-down effect of the intervention
    c) Improved awareness of alternatives to childlessness, including consideration of adoption
2. Perceptions of empowerment
    a) Rejection of stigma
    b) Utilising positive networks in the community
3. Participant understanding of the principles of the intervention
    a) Understanding the learning objectives

b) Impact of homework
c) Impact of the use of stories and analogies

4. Challenges of participating in the intervention.
   a) Time
   b) Access to the intervention
   c) One-to one counselling versus group counselling
   d) A demand of an online version of the intervention

1. Perceived Benefits:

Participants said that the intervention was beneficial to them in many ways. They felt that their coping strategies of dealing with psychological trauma of infertility from self and outside influences were improved. They also believed that they had better bargaining power to negotiate their thoughts and behaviour by rejecting negative vibes and attitudes, and consciously choosing to embrace positive mind-sets.

> *"I think it is good really. It helps one to see things from another perspective… Because it is helpful. Thoughts is something that people do not get to manage. The intervention helps to define your own happiness. To know that what you are going through does not define your happiness".* (P1)

> *"It is something that is needful because while going through this challenge there are so many things that you face. You know, problems of in-laws, friends around and there are instances where you will be having financial challenges. If you can have someone you can share your mind with … and understands what you are going through….its ok."* (P2)

> *"Because I feel like I am going to learn something new… it is very beneficial so that people will not die of thinking. People need to know that when there is life, there is hope and we still have much time and there are many things in this life to do. There are some people that do not have this opportunity that I had, that they do not have anyone to even talk to. Such people will be reached if you make it available to everyone."* (P3)

"If it can help someone like me, then it will help anybody. I used to feel really hopeless and bitter but I can see a big difference in my thinking patterns now". (P7)

Participants also felt that it brought a much needed awareness to their mental health and the importance of maintain good health overall.

"But you know the programme has helped me to see things differently. I now get some things. It really is not a do or die. I appreciate my life. I am more aware of my mental health and how important it is to take care of it. I have a happy home and my husband understands and is very supportive of me… Mental health gets ignored a lot, so it's really refreshing." (P4)

In addition, one participant reported that during consultations clinical staff do not really have the time to enquire about their mental health as a result of infertility. All participants seemed to welcome the idea that the psychological and mental health aspect of infertility management was finally being met within their health care setting.

"You see all these medical doctors, they don't have our time. All these gynaecologist, you can't even ask them any questions. Except [if] you are very lucky and your doctor is a good one, they might take time to explain things to you or even ask you how you are feeling. There some questions you want to ask them, they are not ready to listen… Our consultants don't have time to discuss that with us; they are not ready to do that. 'Their own' [what they do] is to write out drugs and test that you will do and that's it." (P5)

a) <u>Improved Coping Strategies</u>

Coping is an adaptive process that relates to how patients deal with demanding situations outside of their comfort zone (Lazarus & Folkman, 1984). How individuals cope depends on their unique challenges, and their ability to manage the triggers of such stressful situations. In this study, participants felt that they acquired skills to enable them adapt and cope, thereby becoming more resilient in difficult times during their infertility

journey. This enabled them to change their thought patterns and behaviour to adopt positive healthy beliefs and lifestyles.

> *"But the programme is really good … it helps to see things in a different way and I felt that having completed this programme I feel like my mental health has improved a lot better. I just cope better because I have some information I never had before which just puts everything into perspective… Before I was worried about what people will think, that sort of thing. But no more."* (P4)

> *"So before, most of the time I was always deep in thoughts. But when I went for the training, they asked me "what were the things that I liked doing", I told them that I liked listening to music. So most of the time now very early in the morning, I make sure that I play songs that I love… And when I go out, I have a shop and it is always very busy with people coming in and out… When I get home …watch TV, and relax myself and my mind. By 10pm I am tired and feeling sleepy, and I go to bed… so I really do not have the time to think about anything like that and that has been good for me."* (P5)

For some participants, the source of distress did not come from others. It came from self-criticism within the individual due to disappointment or a sense of failure for not being able to achieve something they had believed was a given.

> *"So for me, I went into marriage believing that I was fertile. It was a rude shock to me. And I struggled to cope. I still struggle sometimes but I think about the knowledge that I have gained and that helps me to put things back into perspective. I just kind of reset my brain and give myself a pep talk. That helps a lot."* (P6)

> *"I have a learned a lot of good and useful things from taking part in the counselling classes. The things I have learned have helped me to cope when I am feeling down."* (P7)

b) <u>The Trickle-down effect of FELICIA as an intervention</u>

In addition to helping participants cope personally, FELICIA had a trickle-down effect on other people within the home and the community. They

were able to take what they had learned and teach others within their network. The knowledge passed was beneficial to participants as it created a supportive environment for participants to cope mentally while managing their infertility.

> *"But now, if you ask me anything about [my infertility problem], of course I will tell you and answer you politely 'in which you' [whereby] will also understand that there is no big deal. In fact, there are instances I have to tell other people going through this (because I also have friends going through this challenge) that it's no big deal. Just think right [healthy thoughts]. Once you think right of course things will work out in the end."* (P2)

> *"Ah if I see someone in my shoes, I will recommend it… because it has helped and I have really benefited from it so I will definitely recommend it. I will want another person to benefit from it. So it helps"* (P3)

> "*Yes, very… very beneficial to me. In fact sometimes I have to tell my husband about what I learnt; that this is what they have been teaching us, this is what I leant and he is always like Enhen, Hmmm… He loves it too because he reads my workbook. You know I used to do my homework really well. So when he is at home during the weekend, I will be doing my assignment and he is always like, "what are you reading, what are you doing?" And I'll explain what I am doing to him. So he will take it and read it too. And he likes it."* (P5)

Participants also felt they had developed the ability to recognise unhealthy thinking and behaviour in others, this could be a potential opportunity to sensitise other people going through the same challenges on alternative healthy thinking and behaviours, also creating a trickle-down effect in the community. P1 described how she saw another woman being asked to move places in church to a different location. However the woman took offense and felt that she was being marginalised because she had no children.

> *"But another usher just asked her to shift, as in move inside so that another lady who had a baby could sit closer to the exit. This was actually in consideration for the lady's own convenience, so if the*

baby started crying, she would not have to get up to move for the other woman to get out. But because of the 'weight' on her [psychological burden]. But she was like "Is it because I don't have a child?!" So obviously she has a lot of 'weight on her' ". (P1)

Her ability to recognise unhealthy behaviour in others lead her to be more empathic and understanding of the other woman's plight, thereby indirectly spreading the benefits of FELICIA.

P5 recognised that her husband was distressed and would have benefitted from infertility counselling. The ability to recognise poor mental health in others helped to promote early intervention and helpful recommendations, thereby potentially increasing the uptake of FELICIA and other mental health and support services.

"… One day he was cold towards me. This is very unusual of him. He normally does not play with his food, he likes to eat. I offered him food, he refused to eat. I said "Let's go out", he didn't go. He was just at home, very moody. Later in the day he overcame his feeling and became his normal self…if he had been coming with me, he would has benefited from this programme …He can also learn about the different ways of thinking healthy rather than feeling sorry for himself." (P5)

Participants also suggested increasing access to the intervention for others who did not have the opportunity to participate in the research. They discussed developing online versions that can be easily recommended to other going through infertility challenges. Participants recognised the need for increased access to those who might otherwise have not had the opportunity to participate in the programme. More importantly, they felt that having an online access meant that they could easily share the programme with other infertility patients.

"….which bring back the issue of online versions. For example now if I know someone who need this sort of intervention, and I know I have really 'benefitted' from it, I can say to them… "Madam, check

out this app, it's really helpful. I used it, I think you might find it useful too." (P4)

P6 also felt that FELICIA should be made available to all, not only to infertility patients, because then they could acquire the skills to support other people experiencing infertility related stress. They also felt that it will equip people to cope with infertility, in case they find themselves in that situation.

"Because nobody plans for infertility. And you know some people can just talk anyhow [insensitively], not considering the person's feelings that they are talking to. People can learn that some questions and comments affect us. So they will be more aware of how they speak to people who find themselves with infertility… people don't realise that what they say add[s] to the stress." (P6)

c) <u>Improved awareness of alternatives to childlessness including considerations for adoption</u>

Another benefit of the intervention was that participants felt like they were more aware of alternatives to having children and were more willing to consider adoption. Participants explained how they had felt that considering adoption meant that they had somehow failed. This intervention allowed them to view this option as a positive choice, rather than a last resort when all else had failed.

"Like I had a friend that once told me that if the infertility problem is still there that I can actually adopt a child. And at the time I felt somehow about it. I was annoyed because I thought she was giving up on my chances of having my own. But when I went for the programme I learnt about adoption and I understand that it is an option available to me. I was willing to consider it. So if I later on choose to adopt, I can share my experiences on how it is working for me with someone else." (P5)

"I also started thinking about adoption. It is not that I am planning to. It just never crossed my mind as an option. But now, I think about how I may feel if I had to take that option. I was surprised that I felt like I had choices. I didn't feel like I had failed, no. That was really a surprise

for me. It is only when you find yourself in a situation that you will know what you will really do in that position." (P6)

During the counselling session, discussion around adoption allowed them to discuss their options and clarify misconceptions about the adoption process. They were also able to discuss their feeling about how the public perceptions, negative or positive, would affect them as adoptive parents.

"I did not try to look at things from another angle. I did not consider other options. Adoption was not even a consideration to me even though I work with children. It was just not something I tried to consider for myself. My only focus was having a child of my own. Finish! Now, I am thinking about maybe adopting. I was afraid of what will people say about me and things like that. That was before, now I realise it is all in my head". (P7)

"Although I still really feel bad that I have no child of my own, I am starting to think about adoption. What will I do? How will I do it? That helped me so much because I somehow feel like I have a solution." (P7)

2. Perceptions of Empowerment

During the one-to-one interviews, participants were asked if they felt more empowered after participating in the infertility counselling programme. Although this in itself is a benefit of FELICIA, it has been considered a separate theme with sub categories. During the development of the intervention, empowerment of the participant was a guiding principle, and it was important to determine if this goal was achieved. Furthermore, in this research the findings showed that the empowerment experienced by the participants, was expressed in different forms of rejecting unhelpful stressors, and embracing helpful ideologies, all of which strengthen them psychologically and mentally, to cope with infertility. Treating *empowerment* as a theme allowed the researcher to do clarify in depth, the different ways the participant have felt empowered.

All participants reported that they felt more empowered to deal with internal stressors precipitated from a sense of failure, guilt, and or

disappointment. P4 explained her main source of distress was having no biological child of her own, even though she had two step daughters and described that they had a good relationship. She explained how the intervention enabled her to appreciate her context with a different mind-set that was more appreciative of her relationship with her stepdaughters, irrespective of what others thought about it.

> *"But you know I usually cope very well because I am always so busy. I don't even have time for myself because I work in the bank. So I don't even have the time to think about anything because it's always busy, busy, busy! And I have 2 step daughters who are grown up and they are really good to me… A lot of people assume that they are mine, so people at work do not even know that I do not have children of my own, so it is normal. I don't know if I would be treated differently if they knew…"* (P4)

P5 also explained how she had become fearless after participating in the programme and she was able to give herself credit for her efforts to overcoming infertility and childlessness.

> *"You feel you can do anything. There is no reason to be afraid to face people, there no reason to be shy because you know you are not the only one in it. And it is not as if you are not doing anything, you know you are trying your best to deal with the situation."* (P5)

They also felt more empowered to deal with external stressors which came from marginalisation from other members of the family and community as well as perceived stigma due to their inability to achieve a desired pregnancy. During one to one interviews, P3 recalled how her sister previously made her feel guilty about her inability to conceive because she was aware of her prior history of an induced abortion when she was younger and not ready to start a family.

> *"…It is my own sister, my own blood sister. She is our first born. She knows about my past, so she is using it, you know… Sometimes if she calls me I will not even pick the call. Even my husband was like "…you are very brave now!"…I said yes…I don't even pick her calls again… I*

pick her calls only when I feel like it. Or if she is calling me I will tell her I am busy, even though I am not busy." (P3)

Participants explained that identifying unhealthy thoughts and behaviour and replacing them with healthy, helpful ones was empowering for them to cope with infertility even while receiving treatments. P6 explained that she understood that being self-critical was not helpful to her mental and reproductive health. She was able to identify unhealthy thoughts and behaviour and replace them with healthy and helpful thought and attitude.

"Yes, he (husband) supports me. But I also have to support myself and stand my ground. To be honest I don't have nasty in-laws or people like that around me. I think that I am harder on myself than anyone else. My thinking was no pregnancy, no happiness… In the programme, one thing I picked is that you should give yourself credit for your efforts. I have started learning to give myself some credit and not be so hard on myself." (P6)

Participants also reported that they felt empowered to help themselves and other people that they identify as going through the same challenge as they are. They felt that they were able to offer helpful advice to those experiencing infertility around them.

"Yes, I have a better way of relating with people around me now… I was always touchy. Once you ask a question that relates to that [infertility], I 'will take it up' [pick up on it] and snap! But now, if you ask me anything about [it], of course I will tell you and answer you politely so you will also understand that there is no big deal. In fact, there are instances I have to tell other people going through this (because I also have friends going through this challenge) that it's no big deal." (P2)

a) <u>Rejection of Stigma</u>

"…I decided I was not going to allow their negative comments to weigh me down whereby I will start thinking about what they said or what it could have meant…" (P1)

"Yes I did. My mother in law is my biggest challenge in my home. She used to live with us so you can imagine how hard it was for me…I thank God

she moved back to her husband's house. But I will make sure I discourage her from moving back in… She will not be living with us… even in the programme they mentioned how you can surround yourself with positive networks…Before I was worried about what people will think… I know if I can do this one thing for myself I will be happier and have peace of mind. So yes that is what I am doing to empower myself." (P4)

By rejecting the stigma of infertility, participants reported that they were able to think clearly and objectively about their practical options and solutions to infertility. They felt that they were able to make informed decision that would be beneficial to them and their health as a whole, even to the point of considering adoption if all else fails in the future.

"…Besides I already have a child even though it is not with my present partner. The programme made me to realise that my situation is not that bad and I still have many reasons to be grateful. What if I did not have any?" (P2)

"Yes, I feel empowered. I feel empowered to face people that made me uncomfortable. My mother in-law used to call me sometimes, anytime she call I'll be like she wants to ask again … regarding infertility. Now I feel empowered to face her. I already have that courage to face her and say Mama, the only thing you can do is to help us with your prayers. I say it with boldness." (P5)

"Yes I feel empowered. If you think well of yourself you will reject those who think badly of you. A lot of times we judge ourselves before others have judged us so when anyone says anything horrible to us, we accept it. Especially for us women in Nigeria… everyone assumes it is your fault as a woman." (P6)

"Now, I am thinking about maybe adopting. I was afraid of what will people say about me and things like that… now I realise it is all in my head. And even if they don't approve or talk about me or mock me, I can choose to make that my problem or not. I have the power! … I definitely feel more empowered" (P7)

b) Utilising positive networks in the community

In addition to rejecting ideologies that promoted perceptions of stigma because of infertility, the participants also reported that surrounding themselves with positive environments and people helped them cope better with infertility. They reported that this felt empowering because it improved their mental health, encouraged them to sustain healthy thoughts and behaviour even while actively seeking infertility treatment. They felt that this was beneficial as they were able to make better decisions and informed choices regarding their health, wellbeing and infertility treatments.

> *"In fact, even in the programme they mentioned how you can surround yourself with positive networks. Don't spend time with people who put you down. And it's true. Very true. So from now on anybody who tries to make feel depressed or unfortunate in my own home is no longer welcome."* (P4)

> *"I also have some people around me that help me. In fact there is this woman that my husband and I know, she had her 2 babies in 2 years and she waited 5 or 6 years. A boy and a girl! So I am like why am I worried? We went out to see her and she was just chatting. She has even forgotten about everything she went through. So for me I know it can still happen for me. Especially when you don't even expect it to happen."* (P5)

3. Understandings of the Principle of FELICIA (Ability to Identify, Replace and Practise healthy thinking and behaviour)

At the end of the intervention, participants felt they were able to utilize the 3 steps of Thinking Healthy to bargain their pre-conceived ideologies into positive healthy thinking, behaviour and lifestyle.

> *"… I always tell my husband when I am going that I am going for lecture [laughs]… because I feel like I am going to learn something new."* (P3)

The participants felt that having a step by step, task-based psychotherapy helped them to analyse and understand the concept of cognitive behavioural therapy. The method was also easily applicable to their

infertility life struggles. This meant that they were able to personally identify their thoughts and actions that were unhelpful to their mental and reproductive health, and replace it with practical activities that were helpful. In addition to this they were able to recognise this in others.

> *"I see it as I am not the only person going through the challenges… I see so many people are going through the same thing that I am going through and that it is not the end of life."* (P5)

They also practised the positive lifestyles by adopting it into their daily routine thus converting it into a lifestyle.

> *"… when I went for the training, they asked me "what were the things that I liked doing", I told them that I liked listening to music. So most of the time now very early in the morning, I make sure that I play songs that I love… and I feel very happy."* (P5)

a) Understanding Learning Objectives

Participants were able to learn ways of separating facts from unfounded perception. This allowed them to thinking objectively about the options available to them.

> *"Once you think right, of course things will work out in the end. Because even when you are trying to conceive and you are tensed up. From what I learnt at least… they said your hormones might not also work correctly… I already have a child even though it is not with my present partner. The programme made me to realise that my situation is not that bad and I still have many reasons to be grateful."* (P2)

> *"It has enlightened me to some things I did not know… it has broadened my knowledge in the aspect of isolating myself, people looking at me, maybe people are thinking of me… So it has changed me totally in short. It has changed my idea, my ways of thinking."* (P3)

> *"I learned that what you enjoy doing the things that make you happy, you should spend more time doing it. I have been doing that also. So I am happy. Sometimes I will just be playing music, I will be singing*

and dancing… Like now, I just travelled to my friends place just to spend some time and I really enjoyed myself." (P3)

"I fell that having completed this programme I feel like my mental health has improved a lot better. I just cope better cos I have some information I never had before… even in the programme they mentioned how you can surround yourself with positive networks" (P4)

"I learnt that if I do not think healthy it will even affect me in getting pregnant. It will affect my health…" (P5)

b) Impact of Homework

Participants felt that the homework was appropriate to their needs as it allowed then to reflect on what they had learned and apply it to their daily life struggles. The homework consisted of doing exercises that promoted a healthier lifestyle and mind-set. They were encouraged to identify unhealthy thinking practices and take practical steps in the home and communities to replace such thoughts and behaviour with positive and helpful ones. These changes were documented in their workbook, to be discussed further in their next counselling sessions.

"You know I used to do my homework really well. So when he is at home during the weekend, I will be doing my assignment and he is always like, "what are you reading, what are you doing?" And I'll explain what I am doing to him. So he will take it and read it too. And he likes it." (P5)

"Sometimes when I don't feel good, I write it there. I also use my mood charts to describe how I feel. If I feel sad, or if I am feeling very great that day, I write it there." (P5)

c) Impact of the use of stories and analogies

Stories and analogies were used extensively as a narrative approach in the delivery of the FELICIA intervention. Participants felt that they could relate to them as they could see themselves going through what the fictional character was experiencing. This allowed them to be able to fully analyse the

situation objectively and then apply it to their present circumstances. Participants also found this method helpful as they felt that it aided the flow of discussions during counselling sessions.

> *"Like before now, I was always worried… It is like nothing else matters… But now, going through the programme, reading the stories… It speaks about my situation and I see myself going through what the people in the story are experiencing. You know when you think you have a problem and you hear the same problem from someone else's mouth, it sounds different. You start to wonder about the person. Why is she thinking like that? But then you realise that you are doing the same thing that she is doing…"* (P6)

4. Challenges of participating in the intervention

a) Time

Time was a recurrent topic during the interviews. While some participant felt that time was not a challenge for them as the programme was flexible enough for them to rearrange counselling meetings, others felt that they could not afford the time required to attend all sessions.

> *"I did not have any challenges. Because I was told that even when I travel I should let them know so for me it was ok. Also if she [the public health nurse] is going to be occupied, she will call me that she won't be available and we rearrange for another time. So everything was so convenient and comfortable."* (P5)

> *"The timing to me is kind of flexible enough. Some of the session I feel like they could have been completed daily instead of having to come back every week. So the timing in that sense can be discouraging to a lot of people especially those who do not have the luxury of time…"* (P1)

Although all participants expressed that the programme was beneficial and it was something they looked forward to doing, creating the time to this within their busy schedules was tasking.

> *"The nurse was very nice and helpful. My only problem is that coming every week for 6 weeks was not easy… I work in a bank. I just do not*

have that kind of time on my hands…I was really excited to participate and was only able to because I was off work at that time. If not it would have been impossible for me even though it is something I would have been interested in." (P4)

"I did not enjoy coming every week. Sometimes it was out of my way… I enjoyed our discussions and I benefited from it too. It is just that the whole process of making time to come and see her at UCH was a bit stressful to me. There is a lot of traffic where I live…" (P6)

"I really cannot sit here and fault this programme. The only challenge for me was coming every week for the counselling sessions. It was not so easy for me because of my work. You probably already know this but it took me longer that the 6 weeks to complete my sessions because I had to cancel and rearrange my appointments at least 2 or 3 times." (P7)

b) Access to Intervention

The majority of the participants felt that an increase in awareness and access to the intervention was needed to extend the benefit of FELICIA to others undergoing infertility treatments to benefit. Participants felt that it was important for this intervention to be integrated into their infertility management in order to ensure a continuum of care vis-à-vis their psychological and mental health; in that way complementing the biochemical / surgical care being received for infertility.

"…I wish it was something that could continue and never stop. It shouldn't just stop like that. We need more of this type of programme to get empowered day by day. There are more people coming behind who will benefit from this programme… So this type of programme should be continuous… maybe every 3 to 6 months to update ourselves." (P5)

c) One to One Counselling versus Focus Groups

Participants also thought that there might be an advantage of having focus group discussion rather than one to one counselling. They felt that they might benefit by learning coping strategies from one another. They also felt

that they might discover support groups and organisations that have successfully been accessed by others to cope with infertility stress, especially relating to family, friends and stressors in the community.

> *"…I was really thinking when I was going through the programme that there are some people out there that all they do is worry and could have benefitted from this programme. So if it can be done in larger groups or like a lecture, more people can benefit from this…"* P3

> *…I would have loved to speak with other women facing the same thing… People are looking for who to talk to. And if you find other people in the same shoes as you, you don't feel alone anymore. You can identify with each other, encourage each other, and even make friends that may last forever…"P4*

> *"…we all come together to share our experiences, we can actually learn from one another… I was always there on my own. Just me and the nurse. But if there is someone else there with me, I can learn from them and they can also learn from me and I do not feel alone."* P5

Despite perceiving this as an advantage, participants acknowledge that there is a place for one to one discussions, especially amongst patients in sensitive situations or those who felt more comfortable on their own.

> *"… I am sure some people might be ashamed to discuss with other people so they might benefit better from one to one, but I personally feel that group discussions are better and you are more likely to get more information."* (P4)

d) <u>Provision of an online-version of FELICIA</u>

Some participants felt that creating an online version of the intervention would increase access to, and awareness of, the intervention by others who attend for infertility treatment.

> *"It's possible. If you can do an online version so people can participate even in the comfort of their homes, or at work in their break time, things like that."* (P4)

Some participants expressed their struggle with making time for the intervention out of their busy schedules, stating that an online version might have been less stressful to attain. Although they enjoyed participating in the intervention, the process of attaining this benefit was quite complex and frustrating. One participant expressed that she would have preferred to take part in an online version, she felt that this would have reduced the stress she goes through trying to attend.

> *"… online would really work for me… Because of the traffic in my area, I only go out when I have to…"* (P6)

Discussion

Summary of findings

This research found that FELICIA was acceptable as an intervention, and helped participants manage their psychological health and mental wellbeing, while undergoing treatment for infertility. The participants displayed a thought conversion from negative to positive mind-sets, and felt more empowered to deal with the sources of psychological distress as a result of infertility in their daily lives. Although some participants felt that the programme was flexible enough to accommodate their peculiar need, there was a call to develop an online version of FELICIA, so that that access to infertility counselling can be experienced by other people outside of the research population. All participants expressed that they had benefited from taking part in the 6-week programme. The benefits of the intervention included an increased level of awareness on the psychological aspects of infertility, increased level of considerations for adoption, the ability to identify sources of psychological distress, learning to replace them with healthy thoughts and behaviour, as well as practising healthy thought patterns and lifestyles.

Implications for practice

The major implications from the finding of this study is the need for an increased access to the intervention and maintaining continuity in care for the effects and benefits of the intervention to become sustainable over time.

Improving Access to FELICIA.

Findings from this research show that for many infertility patients, time is a limited resource. The high cost of infertility treatment means that many patients need to be gainfully employed for an income to fund the infertility treatments, especially for those considering assisted reproduction. Therefore, time is a valuable asset that cannot be wasted. Increasing access to the intervention reduces the waiting times that patients will have to endure if they choose to utilise FELICIA to manage their psychological health while undergoing infertility treatments.

E-FELICIA

Participants who took part in the intervention, expressed how having an online version could increase access to the intervention, not only for themselves, but for others who might require it. They expressed how they have been able to identify psychological distress in others and, with the availability of an online version, could have shared the intervention with others. Research show that online psychological therapies are cost effective, could shrink waiting lists, lower the cost of time and travel, and encourage self-management (Marks et al, 2003; Cuijpers & Riperand, 2014). Online therapies also have the capacity to reduce strain on mental health services (Titov, 2007; Spurgeon & Wright; 2010). The development e-FELICIA could be the solution for infertility patient who do not have the time to attend for weekly counselling sessions, but are willing to participate and engage in the psychotherapy sessions to improve their mental health and wellbeing while undergoing infertility treatments, or even after failed treatments. It helps to manage the time required for the intervention from the participant and the health workers' perspective. It also introduces flexibility to infertility counselling.

Delivery of Intervention Strategy

The access to FELICIA is also closely influenced by those who will deliver the intervention, which has an impact on the quality of care being received. Adequate training and supervision are required to equip the health workers to deliver FELICIA. Prior to training, the potential FELICIA facilitators (health workers) need to be assessed to determine that they possess the right personalities and have sufficient knowledge to facilitate the FELICIA sessions.

Training sessions for the facilitators should consist of teachings on the theoretical framework and underpinnings of FELICIA, as well as practical guidance through the use of role plays and visual aids, during training sessions. Facilitators should be tested at the end of the training to determine that they qualify to counsel infertility patients who may be psychologically distressed. This is crucial because incompetent counselling facilitators could have a detrimental effect on the health and wellbeing of the infertility patients. Facilitators will be trained communicate facts and avoid passing on personal unfounded ideologies and beliefs that lack scientific evidence. Promoting positive mental health for infertility patients is the goal of FELICIA, any deviations from this goal should be prevented.

Strengths and Limitations of the study

Although qualitative research is sometimes regarded as biased and subjective, when it is conducted properly, it answers rigorous in-depth questions, with validity and reliability, which would otherwise have been missed using quantitative research methods only (Tobin & Begley, 2004; Anderson, 2010). This study explored the perspectives of the FELICIA programme participants on their views regarding the acceptability and perceived benefits of the intervention. Furthermore, participants were asked their views about perceived challenges, while taking part in the research. There were 5 sets of semi-structured questions (Table 6.1). Although it could be argued that these were 'leading' questions as they sought to ask about specific issues regarding the programme, participants were also asked to give specific examples about their perspectives regarding the topic. Therefore, it

was not enough to answer 'yes' or 'no' to the questions asked, participant were required to give their real life examples of their experience in their own words, thereby gaining an in-depth insight into the issues raised. This can be regarded as a limitation. It can also be viewed as a strength on the other hand as it allows the researcher to measure various aspect of the intervention, which were the guiding principles of the development of FELICIA in Chapter 3, to examine and/or validate, if indeed the intervention is achieving its set out aims and learning objectives.

Another strength of this research is that although there was a list of semi structured interview questions, interviews were not limited to the specific questions; questions were guided and redirected by the flow of the conversion between the researcher and the participants. This aided an easy flow in the direction of the discussions as additional information emerged. For example, participants were asked about challenges faced while participating in the FELICIA programme. In addition to participants identifying their challenges, they also suggested solutions such as an online version of FELICIA programmes, and focus group discussions, to increase access to the intervention. This led to the researcher exploring their perceptions of using these approaches for the delivery of the intervention.

According to Anderson (2010), information derived from human experience is powerful and sometimes more convincing than numerical data. By using a qualitative research approach, the details and complexities regarding dealing with the psychological distress associated with infertility were uncovered. Participants use real life examples, from their interaction with spouses, family, friends, colleagues and the community, to buttress their views and experiences about the positive changes they have made, from before to after the intervention. This enabled the researcher to evaluate progress made by the participants in real time. It also provided explanations for the findings of the previously conducted quantitative research in Chapters 4 and 5. The data collected by these participants informed the research on future directions and findings could be generalized in context, to the larger population.

Role of Bias

The quality of the qualitative research is acutely dependent on, and influenced by the researcher's skills and individual biases and habits, as well as the unavoidable presence of the researcher during data collection, which could affect researcher responses (Anderson, 2010). In this study, the first possibility of bias is derived from the research methodology itself. Due to the subjectivity of qualitative research, the research outcomes could have been influenced. Participants were aware that the researcher is the author of the FELICIA manual being examined, which could have influenced the participants' responses, bringing about a social desirability bias. Also, the participants had just completed a 6-week counselling session that aims to help infertility patients improve upon their coping mechanisms, as well as retrain their mind-set to having a more positive outlook about their infertility. This could have generated a positive attentional bias amongst participants as discussed in chapter 5. Therefore, respondents are more likely to be optimistic and accepting of the intervention than they would have been if they had not participated.

Additionally, participants were expected to recollect and discuss their experiences while taking part in the intervention, which could have resulted in a recall bias. Also, because all participants had psychological morbidities, these group of respondents are more likely to be resilient as they have already had to develop coping mechanisms to deal with adversity. As a result, what they perceive as *good* or *normal,* may otherwise have been criticised by a 'normal' population, who have not had to deal with the same level of adversity, therefore have a lower tolerance threshold for hardship.

Another potential and equally important source of bias was the exclusion of the perceptions of the nurses who delivered the intervention. It would have provided an in-depth assessment of the acceptability of the intervention on the health-workers' side. This was not originally planned at the start of the study as the study was focused on the patient perspective of the intervention. However, as the research continued it became more apparent that the nurses' input would add value in order to determine how feasible FELICIA is in a busy clinical setting. Efforts were made to gain additional

ethical approval to interview nurses. This was difficult due to the requirement of making fresh ethical approval application coupled with an ongoing industrial action at UCH Ibadan, cause considerable delays before that could be collected. As a self-funded PhD student, this delay would lead to an extension in the study period and additional tuition fees which could be not be afforded at the time. Nevertheless, the researcher plans to seek a research grant for a study exploring the nurses' perfectives of the delivery of FELICIA in the management of psychological morbidities associated with infertility.

Even so, the potential sources of bias identified were managed by the researcher ensuring that participants understood the aim of the research, questions being asked as well as the importance of responding as honestly as possible. Participants were also informed that data collected from their response will be used to improve upon the intervention, as it was being tested for its effectiveness in managing infertility induced psychological distress.

Methods Data Collection and Analysis

Telephone interviewing versus face to face interviewing

Although face to face interviews provide information on patients' perspective as well as an insight into meanings through access to participant's body language and expressions, telephone interviews were also considered as appropriate methodology for data collection. According to Harvey (1988), and Fontana et al (1994), conducting interviews by telephone is considered appropriate for short, structured interviews. Evidence shows that participants respond well to telephone interviews due to a perceived sense of anonymity, thus they feel able to discuss freely about sensitive issues (Fenig & Levav, 1993; Greenfield et al, 2000). Although visual clues are absent in telephone interviews which is thought to result in a loss of circumstantial data, research shows that telephone interviews can be used effectively in qualitative research by enabling respondents to feel relaxed and able to disclose sensitive information(Sturges & Hanrahan, 2004; Novick, 2008). There has been no evidence to prove that telephone interviews in research produce inferior qualitative data (Novick, 2008).

During this research, data collection was either face to face, or over the telephone. The researcher had to rely on telephone interviews to reach respondents that would otherwise have been unavailable. Using telephone interviews meant that the body language, that would have been present during face to face interviews, was missing. The researcher did not have it as a cue to probe further, and/or guide discussions during the interviews.

According to Creswell (1998), respondent reluctance is commonplace in interview studies. Furthermore, there is evidence to suggest that telephone interviews are significantly more effective for getting information from participants who are unwilling to take part in face to face interviews for the sake of maintain anonymity, or those who could not be contacted in person (Tausig and Freeman, 1988; Miller, 1995; Sturges and Hanrahan, 2004). All participants were willing to take part, but for some participants, arranging for an interview immediately after 6 weeks of counselling was not possible, and waiting would have caused delays that could have affected the reliability of the research findings.

In order to manage this limitation, all participants had been met in person to arrange interview dates and times, and decide whether they were to be interviewed in person or over the telephone. A through explanation of what was to take place had been explained to the respondents, by the researcher, prior to consenting to take part in the research. Therefore, although the lack of human touch was a limitation, the effect of the lack of their physical presence was minimised.

<u>One to one versus Focus groups</u>

During interviews, some participant expressed that they would have found it more beneficial to have their interviews in groups consisting of other infertility patients, instead of one-to-one interviews. They felt that they might have learned more from others within the group. Although the rationale behind choosing one to one interviews was clearly stated in the methodology section, it brings the question to mind if this in itself produced a limitation with regards to the strength and profundity of data that could have been generated, and by association, the research outcomes.

Future Directions

The research findings of this qualitative research will be incorporated into the evaluation and further development of the intervention. If there is a full randomised trial, it would provide an opportunity to collect data using one-to-one interviews as well as focus group interventions at various stages, thereby increasing the quality of the research outcomes. Qualitative data could be collected from the patients, as well as health workers, to gain a comprehensive insight into their perceptions of the effect the intervention on the health and wellbeing of infertility patients.

Conclusion

Psychological distress as a result of infertility has been a long-standing problem in majority of African societies. FELICIA, an intervention developed to reduce psychological morbidities associated with infertility, has the potential to provide a solution to this problem. The intervention has been well received among this study population, and perceived to be beneficial, empowering, culturally acceptable intervention to those who participated in the 6-week counselling intervention. It is recommended that a larger study to determine the long-term effect of FELICIA as an intervention. Also, evaluation studies are required to determine the feasibility of integrating this intervention into infertility care at the health institution in order to provide holistic care to infertility patients.

Chapter 7:

Summary and Discussions

Summary of Research Findings

This research project was developed to study psychological morbidities associated with infertility within African settings, to identify gaps in infertility related distress management and to develop interventions to manage the identified problems. The research project was planned on multiple levels and it used a mixed methods approach (Table 7.1).

Table 7.1: Summary of Research Project

Method		Study Objective
A	Literature Review	Psychological morbidities from infertility (esp. in Africa)
B	Development of FELICIA [Fertility Life Counselling Aid]	To develop a culturally appropriate counselling programme based on cognitive behavioural therapy (CBT) and Thinking Healthy Programme (THP) to be integrated into infertility care.
C	Cross-sectional study	To determine the prevalence of psychological morbidities amongst patients attending the Infertility Clinic at NHA and UCH, Nigeria
D	Feasibility study of FELICIA	To test a culturally appropriate counselling programme based on cognitive behavioural therapy (CBT) to help couples deal with the stresses of infertility.
E	Qualitative Research	To understand patients' perspectives on the potential benefits of the FELICIA intervention (6 weeks post interventions).

From the literature review in Chapter 2, it was established that infertility had other implications, far beyond being a clinical condition (Table 7.2). It had socioeconomic, cultural and psychological implications for the patient which worsens their health and wellbeing. Evidence also showed that although both men and women contribute equally to the incidence of infertility, women were disproportionately disadvantaged in terms of carrying the physical, cultural and psychological burden.

Table 7.2: Psychological and social consequences of infertility in developing countries (Ombelet et al, 2008).

1. Loss of Social Status	• Fertility = blessing of God; Infertility = curse, punishment • Social status of woman = dependent of number of children (sons) • Burdened with additional social tasks by extended family
2. Social Isolation	• Subject to ridicule, scorn and gossip • Marginalized in family/community • Excluded from community functions • Accusations of 'witch craft', ostracism • Excluded from contact with children
3. Marital Instability	• Unhappiness, sexual dissatisfaction • Alcohol abuse • Migrant Labour • Psychological, emotional and physical abuse • Abandonment/divorce leading to return of bride wealth, poverty, taking on a second wife, strategy to overcome infertility; increased risk of STDs including HIV
4. Loss of Social Security	• Marital instability leading to lack of assistance in domestic tasks • Land claims negotiated through number of children • Lack of old age security • Death of a spouse leading to limited rights to inherit from husband and loss of right to live in deceased husband's compound without the presence of a son.
5. Gender Identity	• Infertility arrests transition from child to adult
6. Psychological consequences	• Most common: guilt, depression, shame, grief, disbelief, sense of worthlessness • Greater width and depth of distress when compared with Western Societies
7. Continuity (Funeral Tradition)	• No child to conduct funeral/mourn for deceased

Although the findings of the literature review showed that infertility related distress is a longstanding problem within African populations, there were no interventions developed specifically to manage them. There was a need to develop a culturally appropriate, low-cost intervention to manage the

psychological morbidities associated with infertility. This led to the development of Fertility Life Counselling Aid (FELICIA), a CBT based intervention based on the Thinking Healthy Programme.

According to the MRC framework, there are four key elements for development and evaluation of complex interventions (Craig et al, 2008). They are (i) development, (ii) feasibility/pilot testing, (iii) evaluation, and (iv) implementation. The development process of FELICIA has been explained in details in Chapter 4. The intervention was designed to be holistic, patient-centred, empowering, culturally sensitive, and to be easily integrated with infertility care within health settings.

Further to the findings of the literature review in chapter 2, it was important to measure the current extent of the problem. This led to carrying out a cross-sectional survey in Chapter 3, to determine the prevalence of psychological morbidities associated with infertility amongst patients attending for infertility treatments. The research took place in 2 hospitals, the National Hospital Abuja (NHA), and the University College Hospital, Ibadan (UCH), both in Nigeria. The findings showed a 43.2% prevalence of psychological morbidities amongst infertility patients attending in both hospitals.

The majority of participants in the cross-sectional survey were women (96%; n=214/224). Attendance by men was sparse due to the context of infertility management for men at NHA and UCH. The majority of the men attended their seminal fluid analysis appointment very early in the day and leave immediately after, not wanting to draw attention to themselves by consenting to take part in a research. The women, on the other hand have to attend pre-scheduled infertility clinic appointments, which usually began at mid-day. This provided more opportunity to engage the female participants in discussions about the research. The men who took part in the research were those who unusually, attended the infertility clinic as a couple and /or in support of their spouses.

Psychological morbidity was measured using the 12 item General Health Questionnaire (GHQ12). The GHQ12 was chosen for many reasons.

One main reason is its ability to measure anxiety, depression and social dysfunction (Gelaye et al, 2015). Another reason for using GHQ12 is that it is short, effective to use in busy hospital settings such as NHA and UCH, as well as widely validated and accepted as a tool to measure psychological wellbeing of patients (Alexopoulos et al, 1988; Gureje et al, 1990; Goldberg et al, 1997; Werneke et al, 2000; Jackson, 2006; Shelton & Herrick, 2009). The results showed associations of psychological distress to be being female, being unmarried, infertility type, longer duration of treatment, and a positive history of domestic abuse.

Following the cross-sectional study, a feasibility study on FELICIA, using an external pilot (randomised controlled) trial, was conducted. The findings showed FELICIA to be an effective intervention for managing infertility related psychological distress. Seven out of eight participants with pre-existing infertility related psychological distress, had no psychological distress after 6 weeks of the intervention. In the control group, which has no intervention, only 1 out of 8 participants had a GHQ12 score indicative of no psychological distress after 6 weeks of observation. A qualitative research was also carried out on those participants who completed the intervention, using one-to-one semi structured interviews. Findings showed that the participants found the intervention to be beneficial and empowering. It enabled them to identify the sources of their infertility related psychological distress, and take steps to manage their thoughts and beliefs, as well as make choice for a better psychological and mental health. By rejecting the stigma of infertility, and making use of positive networks, participants felt more empowered to deal with the sources of distress. Finding were discussed in details in Chapter 6.

Infertility Counselling and other Psychological Interventions used in Infertility Management

In the UK, infertility counselling is well developed. It is a compulsory requirement for all fertility centres to have an attendant clinical psychologist and/or infertility counsellor who are trained specifically for infertility counselling. The British Infertility Counselling Association is a charity organisation and the only professional counselling association in the UK

recognised by the Human Fertilisation and Embryology Authority (HFEA) and British Fertility Association (BFA). BICA provides a platform for interaction, communication, and training of members, as well as providing guidelines for specialist requirement of infertility counselling. In Nigeria and many other African countries, specialist fertility counselling organisations are not readily available, and those who wish to take up infertility counselling do so privately, at a personal and significant financial cost.

It is imperative that fertility health institutions, irrespective of resources available, aim to make the psychosocial and emotional needs of their patients an important focus, all through the treatment experience, while meeting their medical needs (Boivin et al, 2001). Due to scarcity of human and capital resources in LMIC, access to infertility counselling by skilled therapists, is limited. Task-shifting is a strategy identified to overcome human resource shortages, and to scale up mental health care (Kakuma et al, 2011; Padmanathana & De Silva, 2013). The acceptability and practicality of infertility counselling to the population to which it is being provided should also be carefully considered during the design and development of an intervention. In addition to training health workers to scale up mental health care, health professionals should be carried along in the process, in order to promote a smooth running of the intervention and prevent friction within the work force.

In this study, the prevalence of psychological morbidities of infertility was found in a significant proportion of the infertility patients (43.2%), attending UCH Ibadan for treatment, who have no access to psychological support. Therefore, the need for an accessible and culturally acceptable intervention that can easily be integrated into normal infertility care. FELICIA is a public health intervention designed to be integrated into infertility care. It utilises the task shifting approach to train the FELICIA facilitators, using the WHO mhGAP guidelines, under regular supervision by specialist mental health professionals. FELICIA has the potential to tackle other social problems such as social isolation and domestic violence, precipitated by conflicts due to inability to conceive a desired child. Exposure to domestic violence was found cumulatively in 35.7% of participants of this research, a

significant contributor of psychological distress measured as “psychological caseness”. Psychological caseness was also found amongst participants irrespective of whether they had pre-existing children. This shows that the problem of infertility is beyond childlessness, but the extends to the need to meet certain societal expectations, without which can come with dire consequences. In order to provide total care for infertility patients, management of the psychosocial problems associated with infertility should be managed concurrently with clinical treatments. There is a need to provide a platform integrated with health care services that addresses the societal issues of infertility that contribute to stigma and marginalisation of infertility patients.

Design, Feasibility and Evaluation of FELICIA as a public health intervention

The effectiveness of Public health interventions depends on their design, feasibility and evaluation (Speller et al, 1997; Wight et al, 2015). There are available guidelines for development of public health and health care interventions that utilise individual and collective behavioural, social, and psychological lifestyle changes to promote healthy populations (Bartholomew et al, 1998; de Zoysa et al, 1998; Green & Kreuter, 2005; Campbell et al, 2007; MRC, 2008). FELICIA has been developed as a public health intervention that promotes mental and psychosocial health of infertility patients especially in resource poor settings. It has also been tested for its feasibility for use within the population it was designed for, and initial results find it to be effective for alleviating infertility induced stress. The study has identified strengths and weakness of the intervention, and provides information with which to improve upon the intervention for future use and sustainability.

According to Wight et al (2015), poor intervention design produces ineffective interventions, leading to a misuse of scarce public health resources through the implementation of untested interventions, and/or unnecessary costly evaluation programmes. They developed the six essential Steps for Quality Intervention Development (6SQuID) to designing a public health intervention which are: (1) defining and understanding the problem and its

causes; (2) identifying the modifiable causes or circumstances that have the greatest scope for change and who would benefit most; (3) deciding on the mechanisms of change; (4) clarifying how these will be delivered; (5) testing and adapting the intervention; and (6) collecting evidence of effectiveness for thorough evaluation (Wight et al, 2015). These 6 steps are to put into consideration for the future development of FELICIA as an intervention to manage infertility related psychological distress.

Defining and understanding the problem of infertility and its causes

Infertility related stress has been identified as a problem requiring resolutions, through evidence from literature of previous research as well as from the findings of this research. Before the development of an intervention, a health needs assessment is fundamental to understanding patient needs because if patients perceive an intervention be unbeneficial, they are not likely to attend (Wright et al, 1998; Cavanagh & Chadwick, 2005). The prevalence of psychological morbidities identified in this research which include anxiety, depression and social dysfunction, were in keeping with findings of previous research in the same subject area (chapter 2 and 3). The FELICIA programme in Chapter 5, was also tested and found to be effective, beneficial and empowering for the women who participated in the intervention.

Identifying the modifiable causal or contextual factors

According to Wight et al (2015), the second step is to identify the causes or the circumstances that would benefit most, as well as show the greatest scope for change. The modifiable causes identified in infertility related psychological distress are having a rigid mind-set to an inability to conceive at a desired time, which is exacerbated by fixed societal norms and a lack of empowerment experienced mostly by women. This has been shown in this research (chapter 3), by the distribution of psychological caseness across different socio-economic backgrounds irrespective of age, level of education, marital status, or infertility type. This shows all infertility patients are predisposed to having anxiety, depression, and social dysfunction as a result of infertility. In order to increase access to meet the patient needs, the identified causes can be modified by providing low-cost interventions that focus on changing unhealthy and unhelpful thoughts, beliefs and behaviour,

using CBT techniques, such as FELICIA. These interventions when made easily accessible can create a trickle-down effect, by spreading knowledge and addressing unfounded beliefs and attitudes as seen in chapter 6.

Mechanisms of change

Rolling out an intervention for management of infertility-related psychological distress such as FELICIA, has been identified as a mechanism for change in the management of psychological morbidities associated with infertility. It is a low-cost, peer-supported intervention, based on the THP. Strategies that encourage male involvement, such as FELICIA awareness initiatives is an important approach to aid the development of public health intervention for managing infertility related stress. Liaising with microbiological laboratories, andrology clinics, at the recruitment stage for men who attend for seminal fluid analysis, should be carefully considered to increase male involvement when planning for research. In chapter 3 and 5, the disparities in choice between men and women with regards to access to infertility treatment were discussed. This reinforces the stigmatising perception that infertility is 'visibly' a woman's problem. Infertility-related stigma and psychological distress in African communities is largely precipitated by societal norms and expectations. Research shows that a constructive male involvement in health interventions increases positive outcomes as seen HIV and other STD prevention programmes, uptake of contraception, intimate partner violence, perinatal mental health programmes and other reproductive health programmes (Barker et al, 2007).

Another mechanism for change is widening access to FELICIA for all infertility patients, from all works of life. For many infertility patients, the high cost of treatments means that patient need to stay working to secure a steady flow of income. In Chapter 6, the qualitative research showed that time is a limited resource and participant felt that they could benefit from online versions of psychological support. High infertility costs as discussed in chapter 2 and 6 show meant that participants require gainful employment to pay for their treatments, and therefore may not have the time or chance to physically attend counselling. Thus, the development on internet-based FELICIA should

be considered for the future to cater for those patients who do not have the time to attend for counselling every week.

Delivery of intervention

The anxiety, depression and social dysfunction identified amongst infertility patients need to be addressed by mental health workers who have the adequate skills and knowledge to deal with such problems, even in busy clinical settings. Research shows that although depression, in particular is the third leading global health problem, majority of those affected go untreated in LMIC because of a lack of mental health professionals (Wang et al, 2007; Saraceno et al, 2007; Murray et al, 2011). FELICIA was designed to be delivered by nurses at the infertility clinics and public health nurses who will be adequately trained and supervised to deliver FELICIA, using the WHO mhGAP guidelines; these have been discussed in detail in Chapter 3 and 6. Although the nurses' perspectives could not be explored in this particular study as discussed in chapter 6, the results of the research in chapters 3 and 5, as well as the participants" perspectives in chapter 6, show that an intervention such as FELICIA is well received and culturally acceptable, therefore strategies need to be put in place to increase access to all infertility patients.

One option to improve access is the development online version of FELICIA. Concerning the development of e-therapies, careful consideration must be given to the method of delivery to avoid patients being left to their own devises without professional supervision. The development of an online version of FELICIA would require a multidisciplinary team of high-level specialists, middle level health professionals, as well as lay people, to provide a balanced view of ideas and concerns. The choice of having an e-version of FELICIA, could provide the much-desired convenience, in addition to accessibility as demanded in chapter 6. It could also provide anonymity for some patients where it is safer for them to take up this option.

Testing the developed intervention on a small scale

According to the six essential steps for quality intervention development by Wight et al (2015), after initial intervention design, feasibility testing is required to test the interventions and identify adaptation that need

to be for improvement. We chose to try a paper version in a large infertility clinic, rather than an online version, and/or conducting the intervention in the community. In this research project, a feasibility study was conducted and the findings are discussed in details in Chapter 5. Further research is required to develop and test other methods of delivery of FELICIA for their feasibility and efficacy. Prior to testing of the intervention, a more robust research is also required to determine the prevalence of psychological distress amongst infertility patients and screen for those who require an intervention. In chapter 3, the results of the cross-sectional survey showed weak associations between the different correlates/variables and presence or absence of psychological caseness. This emphasises the need to consider more robust research methodologies in order to obtain valid results that are representative of the population. Other methodologies such as retrospective cohort study using patient health records and case notes in addition to cross-sectional survey is required to determine the true prevalence rather than relying of patient self-report to screen for eligible participants of the feasibility/pilot study.

Evaluation and implementation

The ability to identify the effective components of an intervention, for whom the intervention is effective, as well as the context in which optimal efficacy is observed, are essential to the improvement and sustainability of health interventions (Steckler & Linnan, 2002). Based on the outcomes of this research, it can be deduced that FELICIA has the potential to reduce infertility related psychological distress, who are willing to take up infertility counselling. It can also be construed that implementing FELICIA for participants locally will improve uptake rates of the intervention. However, males were grossly underrepresented in this research. More research is needed to understand why, and how to improve male participation and uptake of the intervention, in addition to improving acceptance by male and female patients who are resistant to unfamiliar psychological therapies.

Continuity of the psychological care of infertility patients

Continuity of care is regarded an important aspect of high quality to be viewed from a multi-dimensional perspective of the health professional, the

health provider and the patient (Gulliford et al, 2006; Biringer et al, 2017). Although continuity of care was previously envisioned only from the patient perspective of an ongoing professional- patient relationship, patient care needs have now conventionally advanced into a multi-disciplinary approach to care.

Biringer et al (2017), identified five themes representing experiences of continuity of care; these are relationship, mutuality, timeliness, choice and knowledge (Fig 6.1)

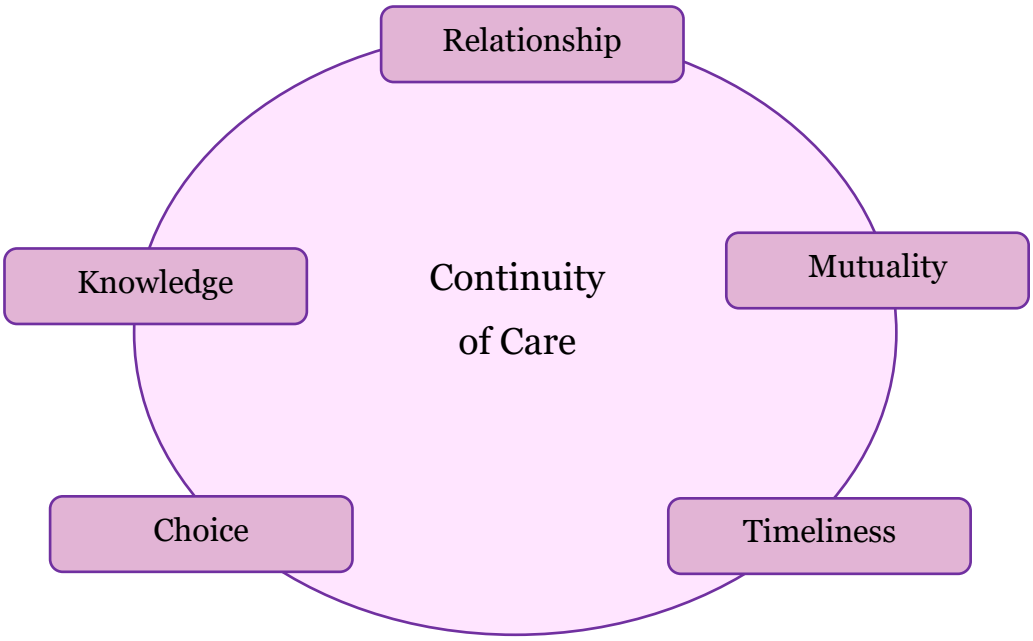


Fig 7.1: Dimensions of service users' experiences of continuity of health and social care (Biringer et al, 2017)

An important aspect of the effectiveness of FELICIA is the potential for continuity in care and support for infertility patients throughout the time they are undergoing management which could be medical, psychological and social. The reason for the need for medical and psychological support has been made clearer in this study. Social support is needed also, when infertility patients have to come to the decision of choosing, surrogates, sperm or egg donors, as well as making decision regarding the choice to adopt. Making these decisions without adequate care and support could precipitate psychological distress and mental ill health on the long run.

Relationship

Maintaining a trusting and continuous relationship with the counsellor over time fosters perceptions of trust and safety. However, it would be helpful if the patients could meet the same FELICIA counsellor as much as possible. For the patient, having to relive their experiences over again with different health workers can be challenging and aggravating. This aggravation could lead to anxiety and poor communication from the patient, thereby leading to difficulties for the health worker. Understandably, there are times when there might be a change in the health worker handling a patient's case file for various reasons. The new health worker should be well familiarised with the patients history. The patient on the other hand should be promptly informed of these changes that is to be expected to enable a smooth transition.

Timeliness

Timely access to help and support when needed, without long waiting times, improves patients' experience of care being received. For the infertility patient to benefit from FELICIA, there needs to be an increase in access to the intervention in terms of the promptness of arranging counselling session and the availability of trained personnel to deliver this intervention as and when needed. The long wait experienced by infertility patients who might require psychological or mental health support could further worsen their symptoms. The idea of having other ways of accessing the intervention to increase timely access were also discussed by the patients. Online access was welcomed by participants. While this concept is modern and practical in this era, there are pros and cons to be considered which will be discussed further in this chapter.

Mutuality

Equity in the decision-making process of care by the health worker and the patient was another theme identified to improve continuity in care. The FELICIA intervention was set up with the idea of equal engagement between the patient and the health worker. Meeting are pre-arranged with the full participation of both parties and all activities during the counselling sessions such as discussions, homework and goal setting are mutually agreed. Patients are expected to take up initiatives to make healthy changes to their lifestyle that promotes good mental health and wellbeing. This improves the

confidence of the patient and promotes a trusting relationship with the health worker, thereby increasing sustenance and continuity in care and support being received through FELICIA.

Choice

According to Biringer et al (2017), having the choice, from a variety of options, and to influence the decision-making process of care encourages continuity in care. It makes the patient to become more invested in committing to the treatment therapy being provided. In FELICIA, patients had the choice of choosing which of the counselling session was tailored to meet their need, with the support of the health worker. Their input was central to the decision-making process of the structure and content of their counselling session. This had a positive effect on their acceptance of the intervention where by all participants in the study felt that the intervention had been beneficial and empowering for them.

Knowledge

Knowledge is an important aspect of the continuity of infertility care. For FELICIA as an intervention, knowing what is going to happen during counselling sessions is reassuring for the participants, in addition to having a choice on which counselling sessions to participate in. During the counselling sessions, the participants were given information about the topic of discussion through the learning objectives. Furthermore, their understanding of what was being discussed was tested through activities, and homework. The positive patient to health worker interactions, coupled with having an informed choice gave the participants a sense of security, thereby making it easier for them to accept and engage constructively with the intervention.

When FELICIA is used, the health workers delivering the intervention have to be knowledgeable on topics and concerns surrounding infertility. They also have to be aware of organisations that can support participants going through one issue or another for example, legitimate adoption agencies, domestic violence support organisations, legitimate assisted reproduction agencies, etc.

Strengths of the Research Project

1. Locally done

A major strength of this research project is that it was locally conducted among the population that will directly be affected by outcomes of the research, including its benefits. Although this research was carried out in Nigeria, it was done to high standards because the research protocol was developed to satisfy ethical requirements in both Nigeria and United Kingdom. Sustainable development is best achieved through the use of local knowledge, services and resources (Akegbejo-Samsons, 2009).

2. Patient-centred research

Patient-centred outcomes research (PCOR), provides an opportunity for patients to provide recommendations for every aspect of the research process (Sofolahan-Oladeinde et al, 2015). In this research project, the women who participated in the intervention were asked about their views regarding the intervention, its benefits, and mode of delivery as well as perceived challenges. The outcome of the research will provide recommendations for further development of the intervention, through community based participatory research (CBPR) to produce optimal efficacy.

3. Evidence-based research

The psychological health of infertility patients is important for their capacity to make decisions regarding their health, wellbeing and family life choices. By providing patients with evidence-based information, they are empowered to make the right decisions. This research project was based on scientific evidence from the identification of the need for psychological support for infertility patients, to the development and testing of the FELICIA intervention. The initial findings of the cross-sectional survey conducted to determine the prevalence of anxiety and depression amongst the infertility patients at UCH and NHA, in Nigeria were both in keeping with previous prevalence studies in Nigeria. Secondly, the FELICIA intervention itself is based on THP, which has been shown to be effective for the management of perinatal depression (WHO, 2015). Furthermore, FELICIA uses other evidence based approached for its development, these are the use of stories

and analogies as well as the task-shifting method (Blenkiron, 2005; WHO, 2006).

4. Developing partnerships

During the research progress, research collaborations were developed between the University of Liverpool, UCH Ibadan, and NH Abuja, through engaging with a multi-disciplinary team of health professionals and patients. This provides a platform for further health research and sustainable programme development in the future between professionals at various career stages and disciplines, as well as patient groups.

5. Awareness of the research context

The researcher is a British-born Nigerian health care professional, with working experience in health-related research in both Nigeria and the UK. Having a foot in both worlds allowed her to carry out research with a comprehensive knowledge and understanding of the research contexts and requirements in both settings. The researcher developed the skill and capacity for development of complex health interventions in resource wealthy health care settings and was able to apply those skills and strategies to develop a holistic health care intervention for a resource poor setting. The researcher has an in-depth understanding of the Nigerian sociocultural circumstances of infertility patients, and was thereby able to apply this knowledge to the research and programme development. This led to FELICIA being accepted and perceived to be beneficial by the infertility patients in Nigeria. This also produced a pragmatic and efficient channel communication between members of the research team here in the UK and in Nigeria.

6. Supervision

Academic supervision was another strength of this research project. This is as a result of the variety and wealth of expertise overseeing this research project. As a PhD student of University of Liverpool, carrying out a research in Nigeria, it was a requirement to have academic supervisors in Liverpool and onsite supervisors in Nigeria, all of whom were seasoned researchers in their various fields. This led to having up to 4 supervisors by the end of the research project. At first, the research project started with 3 academic supervisors (2 at

Liverpool, and 1 in Nigeria). However, when it was decided that the study be moved from NHA to UCH, it led to the inheritance of another supervisor at UCH. While having 4 supervision could have been a limitation by causing a clash of ideologies, the student had to study each expert to understand their skills and what they can 'bring to the table'. For example, knowing who to ask for advice about what, was a useful skill which prevented a conflict of opinions and principles.

Limitations of the Research Project

1. Delays in participant recruitment

Recruitment during the research was interrupted by many factors which included distance, limited funds, and other logistic limitations. The initial research plan was to carry out all stages of this research project at NHA. However, the distance of Abuja to the residence of the researcher in Lagos created a significantly increased travel and living cost, which led to difficulties in conducting the research. Following a recommendation by the onsite supervisor at UCH, it was then decided by the supervision team to move the study to UCH in Ibadan, which was closer in proximity, after completing the cross-sectional study at NHA. UCH also had similar qualities to NHA as a tertiary health care institution, treating infertility patients in Nigeria. The expected similarities in the two settings were reinforced in the findings of the cross-sectional study, done to determine the prevalence of psychological morbidities amongst Nigerian infertility patients in Chapter 4.

However, relocating the study led to delays in commencement of the feasibility study as well, which led to only 16 participants being recruited for the feasibility study in Chapter 5. Despite preceding events, results in the feasibility were overwhelmingly positive and it was felt that having more participants was unlikely to add more value to the research outcomes.

2. Bias

The role that bias played in each of the research studies have been explained in detail in Chapters 4, 5 and 6. Self-report bias has been identified as the researcher had to rely on participants' own responses in the cross-

sectional and feasibility studies, as well as during on-to-one interviews in the qualitative research, during data collection stages.

Another source of bias could have come from the researcher being overly familiar with the community in which the research is taking place in Nigeria. The researcher identifies as a member of that community in diaspora, thus it was comfortable and effortless to understand meanings and expression of respondents, as well as the politics of the work place in a Nigerian health care setting, as well as in the community. While this may be perceived as a strength, it also carries the risk of the researcher making generalised assumptions about patient responses and experiences, and their implications. The researcher manged this bias by making sure to clarify what is being said or implied by the participants, the health care professionals, administrative staff, and other lines of work encountered, at every opportunity, to avoid preconceptions.

Attentional bias has also been identified as potential source of bias, which is the tendency for participant perceptions to be affected or influenced by their recurring thoughts, leading to inability to consider alternative thoughts or possibilities. From the finding of this study in chapters 2, 3, 5, and 6, infertility patients in Nigeria are highly exposures to stress and adversity as a result of infertility. This causes a heightened sensitivity to negative stimuli, which further predisposes this group to psychological morbidity even if infertility were absent. In chapters 5 and 6 in particular, patients who have participated in the intervention also show marked reversal of psychological caseness which could indicate an unrealistic bias towards positive stimuli. Therefore, in further research, the attentional control of participants should be measured as well as its association with the research outcomes, in order to need to determine the relationship between regulation of attention and the efficacy of the intervention.

Memory bias is also a source of bias as the research heavily relies on self-report of participants. For infertility patients, the high exposure to psychological distress and physical discomfort of infertility medical treatments, can cause patients to be in a perpetual pensive state of mind. As a

result, patients are conditioned to develop coping mechanisms such as selective memory which is source of memory bias. In chapter 3, there was a high rate of no response during the cross-sectional survey up to 11%. The lack of response could have been a way for participants to avoid confronting certain sensitive issues or could be because they really could not recollect at that point in time. Apart from selective lack of memory, it also could mean that the real answers to those questions were deemed shameful by the participant, leading a source of social desirability bias as discussed in chapters 3, 5, and 6.

3. Distance

Distance was another significant limitation to this study. The research being based in Liverpool, and carrying out research in Nigeria, led having to make multiple trips to Nigeria, within limited resources. The researcher had to device means of carrying out the research to optimal standards, while having a healthy work-life balance. Completion of interviews by the telephone became a helpful means to completing the research process in a timely manner, because further travel was not possible. It was also important and helpful to have an onsite supervisor, as well as a cohesive research team in Nigeria, who continued the work when the researcher was not in the country. Again, the researcher being a member of the local community was also helpful because gatekeepers at every stage could be easily identified and spoken to in person to facilitate the efficient running of the cross-sectional study, the feasibility study and qualitative research.

Another issue affected by distance was the supervision of the nurses who delivered the FELICIA intervention. Because the participants were recruited into the study at different times, the period between recruitment, the 6-week counselling, and measurement of outcomes for all participants was extended up to 7 months. This meant that there were times when the researcher was not present in the Nigeria, while the study was ongoing. Although the nurses all received a 2-day training on FELICIA before commencement of the FELICIA programme, supervision was necessary to ensure that they followed the guidelines of the intervention. The researcher had to rely on the telephone as a means of supervising the FELICIA facilitators, along with the use of an onsite supervisor. The nurses also maintained regular

weekly telephone contact, with the researcher to update her of the progress of the programme and the participants taking part in the intervention.

In addition to supervision of nurses, it would have added more value to the research study if the nurses' perspective had been sought to understand issues relating to the delivery of the intervention on the part of the health care providers. Their exclusion led to a limitation in providing an in-depth assessment of the acceptability of the intervention on the health-workers' side. The reasons behind this limitation have ben explained in details in chapter 6. Further research is required to address this gap in data in order to determine the feasibility of FELICIA, an intervention for managing psychological morbidities associated with infertility in busy clinical settings.

Future Directions

The outcomes of this research project show that further research and development is required to develop the intervention to optimise benefit and access for all patients. This can be addressed in 3 ways: improvement to the FELICIA programme itself, further robust evaluation of FELICIA, and, in time, preparing for scaling up the programme.

1. Improving the FELICIA programme

During the feasibility study, it became clear that the programme was quite gender-specific, despite many of the solutions being in the hands of the male partners. Gender refers to the socially constructed roles, expectations and definitions that a given society considers appropriate for men and women (WHO, 2007). Evidence shows that the response to infertility is influenced by gender differences and gender specific diagnosis, which causes disparities in coping strategies amongst men and women (Nachtigall et al, 1992; Gibson & Myers, 2000). Williams et al (1992) suggested that women carry a greater physical and emotional burden of infertility in terms of medical treatment and physical reminders such as the menstrual cycle, which the men do not experience. Studies also suggest that while women were more likely to cope by confronting infertility, accepting responsibility, and accessing social support, men on the other hand coped through self-control,

dissociating from infertility and calculated problem-solving (Peterson et al, 2006). Research shows that although coping mechanism may differ, men and women both benefit proportionately, from counselling and psychological interventions for infertility related distress (Boivin, 2002).

It is therefore necessary that the differences in the coping mechanisms between men and women in relation to infertility, should be incorporated into the development of programmes for the management of psychological wellbeing of infertility patients. In the same way, improved male involvement in counselling programmes for infertility patients such as FELICIA, is more likely to be beneficially for all sexes and its positive effects sustainable over time. Strategies that attract men and other less motivated patients, who would otherwise benefit from infertility psychotherapy, should be incorporated into future evaluation and implementation of FELICIA, for all to benefit. This would reduce the burden of infertility induced stress for infertility patients.

A second area for improvement is the need to incorporate different ways to deliver the FELICIA programme. In addition to individual counselling, couple therapy and facilitated support groups should be included into further development of the FELICIA programme. Incorporating different counselling groups proportionately increases access and addresses the needs of men and women with infertility. Examples of such groups are couples groups, men only and women only groups, counselling according to diagnosis or treatment modalities, surrogacy or adoption counselling groups, etc. Each counselling session in the FELICIA manual will be evaluated to determine whether participants will benefit more when counselled individually, or in relevant groups, in order to optimally achieve learning objectives of each session.

2. Future Research

The widely regarded gold standard for estimating the cause and effects of public health interventions with defined outcomes and population, are randomised controlled trials (Campbell, 1999; Shadish et al, 2002). A full RCT is required to establish evidence that the FELICIA is working as expected, and achieving the set-out outcomes, with the positive effects sustainable over time, without causing any serious unintended effects or social and health

inequalities considering patient care. The methodology of the development of the larger RCT has been discussed in detail in Chapter 5. Also, a different methodological approach to data collection for prevalence study of infertility should be considered. In addition to survey questionnaires, a retrospective review of patient clinical records of their infertility history, in addition to self-reported questionnaires, could provide more robust data and results. A larger sample size of infertility patients that capture the male population would also be required to increase the probability of producing valid results. An improvement in recruitment strategy is required to increase male participation in infertility research. Data collection should expanded to multiple infertility treatment facilities, including, private and public health institutions.

This research project used the GHQ12 questionnaire as a measure of psychological morbidity amongst infertility patients. While GHQ12 is a widely accepted and validated tool, used in various clinical settings, there are more specific tools used to measure fertility related distress and the capacity to cope with infertility. These are the Ways of Coping Questionnaire (WCQ), Fertility Problem Inventory (FPI) and the Dyadic Adjustment Scale (DAS). The WCQ is a 66-item questionnaire used to measure the coping strategies in response to the diagnosis of infertility (Folkman *et al*., 1986). It measures 8 components namely: *confrontative coping*, *self-controlling*, *seeking social support*, *accepting responsibility*, *escape*, *avoidance*, *planful problem-solving*, and *positive reappraisal* (Folkman et al, 1986). The FPI is a 46-item scale that measures infertility stress, using a 6-point Likert scale to determine 5 subcategories of infertility stress, which are *social infertility stress*, *sexual infertility stress*, *relationship infertility stress*, *individual need for parenthood*, and *individual's feelings about a child-free lifestyle* (Newton et al, 1999). The DAS is a 32-item tool used to measure marital adjustment by assessing *satisfaction*, *cohesion*, *consensus* and *affectional expression* (Spanier, 1976). Lower DAS scores are predictive of predisposition to domestic violence, depression and poor communication in marital relationships (Stuart, 1992).

The WCQ, FPI, and DAS demonstrate high validity and reliability scores within the North American population, and would be ideal to measure infertility related distress amongst infertility patients. However, these tools have not been validated within African populations, therefore validity and reliability test should be completed before its use within an African setting.

Finally, further research is required to address this gap created by the exclusion of nurses' perspective in the qualitive and quantitative research data in order to determine a comprehensive view of the feasibility and perceptions of the intervention for managing psychological morbidities associated with infertility in busy clinical settings.

Conclusion

Psychological morbidities have been proven to be common amongst infertility patients as shown by this research project as well as previous studies. FELICIA is a novel psychological intervention designed to address and reduce infertility induced psychological distress, within resource-poor African settings. The results of this initial study suggest that FELICIA may have the capacity to reduce anxiety, depression and social dysfunction, developed as a result of the detrimental physical, emotional and social effects of having infertility. It may also have a role in alleviating these mental health symptoms and empowering women to reject infertility related stigma, abuse and promote positive relationships in the home, family and the community. Although FELICIA set out to target all infertility patients, male and female, the outcomes of the research appear to suggest that women were more accepting and/ or had better access to the intervention, thereby benefited more from the intervention.

The qualitative study suggests that there was also a positive trickle-down effect in the community. FELICIA participants felt empowered to discuss what they have learnt about managing their psychological and mental health with their partners, family and friends, as well as identify others in need of psychotherapy, recommending the intervention.

Despite the findings of this research project showing positive indications that the intervention works, future research is needed for further

development of the programme, as well as testing in a wider population. This would provide a reliable measure of its efficacy as a tool for managing and/or reducing the psychological morbidities associated with infertility within African populations.

Chapter 8:

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Appendix 1

Key findings of literature search of major scientific data bases for the development of the FELICIA

	Author	Year	Methodology	Key findings
1.	Domar et al	2000	**Randomised control trial:** An RCT study to determine whether group psychological interventions could prevent higher levels of psychological distress experienced by infertile women as infertility duration increases. Women (N=184) were randomized into 3 groups: a cognitive-behavioral group, a support group, and a control group.	The cognitive-behavioural and support participants experienced **significant psychological improvement at 6 and 12 months** compared with the control participants. The cognitive-behavioural participants experiencing the greatest positive change.
2.	Mabassa	2000	**Qualitative research (N=76):** Chapter 4 of *Psychotherapy and African reality* book. The study investigating the views	The findings show that the stigmatising effect of infertility was worse for women because they were assumed to be the cause of infertility in a relationship. These women did not receive social support. Men were protected from exposure as the cause of infertility.

			of Black South Africans regarding infertility.	Younger respondents were more open to the idea of formal adoption than the older ones.
	Lee et al	2001	**Survey:** Cross-sectional study to measure differences in levels of distress, marital and sexual satisfaction in husbands and wives diagnosed with infertility, using the Chinese version of the Infertility Questionnaire (CIFQ).	Results showed female members of couples in which both partners were infertile expressed less marital and sexual satisfaction than their husbands. There were no differences in marital and sexual satisfaction were found between wives and husbands with unexplained infertility. Wives with a diagnosed female infertility expressed higher distress to infertility, than their husbands. They also experienced lower self-esteem and less satisfaction in acceptance by in-laws than wives experiencing a diagnosed male infertility. There were no differences in psychosocial responses were found among husbands, regardless of the diagnosis The research shows **gender differences in responses to infertility** and this should be considered when counselling infertile couples.
3.	Upton	2001	**Review Article:** An article advocating the significance of infertility as lens through which the	The paper identified infertility is an invisible demographic variable.

			cultural constructions of gender and health may be viewed. Based on studied in Northern Botswana.	In Botswana, statistics suggest a high rate of extramarital fertility and a rapidly increasing HIV infection rate. **The paper makes a case that a more social and ethnographic understanding of the importance of fertility can lead to a better understanding of why some population policies have not been effective.**
4.	Van Balen & Inhorn.	2002	**Book Chapter from book titled *"Infertility around the globe":***	The chapter summarises the book which uncover the "lived experiences" of infertility and childlessness around the world
			An review article as an introductory chapter titled Interpreting Infertility: A View from the Social Sciences	It covers collective and individual experiences of living with infertility, describing the ordeal of the "infertile" as a *"medical and emotional road of trials"*. The book highlights how **infertility definitions have been generalised based on western ideologies which have little or no relevance for the people living with infertility in various communities around the world.**
5.	Chen et al	2004	**Prevalence study (N=112):**	High prevalence of depressive and anxiety disorders were identified among women who visited an assisted reproduction clinic for a new course of the treatment.
			The prevalence of specific anxiety and depressive disorders were diagnosed among women visiting an assisted reproduction clinic for a new course of treatment,	Results showed **40.2% had a psychiatric disorder** - Generalized anxiety disorder (23.2%), major depressive disorder (17.0%), and dysthymic disorder (9.8%), irrespective of age, education, income, years of infertility or a previous history of assisted reproduction.

			using a structured interview, the Mini International Neuropsychiatric Interview (MINI).	
6.	Dutton & Nicholls	2005	**Critical analysis:** A critical review of the feminist theory of intimate violence Data was collected from incidence studies reporting levels of violence by female perpetrators higher than those reported for males.	Key finding of the review article highlight the high levels of unilateral intimate violence by females to both males and females. Findings showed an **underreporting of domestic violence and victimisation towards males** when compared with level of reports made by females. Men tended not to view female violence against them as a crime.
7.	Dutney	2006	**Book Chapter:** A chapter *in Clinical Obstetrics and Gynaecology* book, describing the effect of religion on family formation and impact of infertility on religious people.	Family formation was identified as central in all religions examined by the review thus **infertility is experienced as a religious crisis.** **Clinicians and policy makers need to accommodate the type of impact of religion on infertility and the acceptance of Assisted Reproductive Techniques (ART).**
8.	Ameh et al.	2007	**Cross sectional study (N=233):** A study involving women attending for infertility	**Results showed 41.6% (n=97) of the women had experienced domestic violence as a direct result of infertility**.

			treatments in 3 Nigerian hospitals over a 12 month period.	The main perpetrators were the husbands in 48.5% (n=47) and female in-laws in 32% (n=31); according to respondents The prevalence of domestic violence was not significantly affected by the level of education, marriage type, parity or the duration of infertility.
9.	Donkor & Sandall	2007	**Survey (N= 615):** A survey conducted face to face to investigate relationship between perceived stigma and infertility related stress among Southern Ghana women.	The results showed 64% of women in this sample felt stigmatised. Multiple regression analyses implied high levels of perceived stigma were associated with increased infertility-related stress. Women with higher levels of education felt less infertility-related stress. The presence of an existing children, the number of years spent in infertility treatment and the type of marriage (monogamous/polygamous union) were less important in predicting stress. Finding showed **improved social status of the women minimised the impact of stigmatisation** on these women
10.	Antai & Antai	2008	**Survey (N=3911):** A study examining the predictors of rural women's attitudes in Nigeria toward	The article highlights that residency in rural areas is associated with increased acceptance of IPV. Findings were suggestive of social, religious, and cultural influences in the women's attitudes towards IPV.

			intimate partner violence (IPV).	Women resident in the three northern regions, the south-south region, Muslim women, women with low levels of education and low household wealth were more likely to tolerate IPV; a reflection of the socio-economic, cultural and religious oppression they experience.
11.	Castro et al.	2008	**Survey:** To examined the degree of women's empowerment and autonomy in relation to their partners in Mexico by logistic regression analysis	Logistic regression analysis, with physical violence (IPV) as the dependent variable and several explanatory variables were grouped into four categories- sociodemographic factors, nuptiality and fertility, antecedents of violence, and indicators of women's empowerment. Key findings showed **access to resources meant to empower women did not automatically decrease the risk of violence**. Recommendations for specific interventions tailored to different groups, to stop the cycle of violence.
12.	Hollos et al	2009	**Mixed methods research:** Involving qualitative methods (in depth ethnographic interviews) and quantitative approaches (survey comparing infertility and fertile groups of women) in Amakiri and Lopon communities in Nigeria.	The in-depth interview results show **childless women face cultural, and socio economic hardships** and are not recognised as attained full womanhood among patrilineal kinship community in Amakiri. Unlike the Lopon community where kinship is double unilineal (both patrilineal and matrilineal); here, infertile women receive support from maternal kin as well as voluntary associations serving as support groups. In both communities, fertility is perceived as a central fact of life.

				The survey data confirmed significant differences between the life experiences of infertile and fertile women in the two communities.
13.	Ofovwe & Agbontaen-Eghafona	2009	**Review Article:** A review article on infertility as a social problem and a risk factor for gender based violence (GBV) in Nigeria.	**Infertility spans beyond a being a clinical condition; it has varying cultural definitions which does not always refer to an inability to give birth to a child.** Inability to have the desired number of children, not having sons or not being pregnant soon after the commencement of sexual activity constitutes infertility within some cultures. Children are perceived as a major reason for marriage Consequences of infertility highlighted are psychological, social and physical suffering where women are made to bear the burden of infertility irrespective of its aetiology, leading to GBV.
14.	Oladokun et al.	2009	**Focus group discussions:** 12 focus group discussions involving three communities in Ibadan, Nigeria, from May to July 2008.	**Key barriers to adoption identified in this community were cultural practices, stigmatization, financial implications, and bottle-necks in the adoption procedures.** Participants made suggestions to reduce the barriers and negative attitudes. These were advocacy, community mobilization and enactment of supportive law that will protect all parties involved

15. Weinger	2009	**Qualitative research:** One to one interviews of Cameroonian women who spoke about the suffering they experience as 'infertile' woman	The **women reported that even though they raise children, they are still considered childless because of not producing biological offspring of their own**. Due to their infertility, and to avoid abuse and derogatory comments, these women have to be agreeable and charitable, or they would receive the wrath of others in the community. They are treated unfairly and expected to work longer hours than their counterparts for their pay. Coping measures include developing quick and ready responses when attacked verbally, raising non-biological children, religious faith and prayer, carefully conforming to societal norms and expectations as well as self-counselling.
16. Cui	2010	**Case study:** A woman with secondary infertility in Uganda who suffered several miscarriages and ectopic pregnancy.	**Infertility prevention and care remain neglected and ranked low on the public health priority list** in especially low-income countries with high population pressure. Low fertility is becoming increasingly common globally, confounded by ageing populations and urban lifestyles where women are having their first babies at older ages.

17. Van der Broek	2010	**Report:** A summary of the proceedings of a campus workshop of the Psychology and Counselling of the European Society for Human Reproduction and Embryology (ESHRE)	Infertility counselling offers the opportunity to explore, discover and clarify ways of living more satisfyingly and resourcefully when fertility impairments have been diagnosed. The Heidelberg Fertility Consultation Service is presented as a framework for individual and couples counselling; it highlights important issues in counselling patients individually and within groups. **The workshop is beneficial for mental health professionals new to the field of reproductive technologies as well as those in other areas of mental health counselling clients with fertility disorders.**
18. Ardabily et al	2011	**Cross-sectional survey (N=400):** Women with primary infertility attending a reproductive centre in Tehran, Iran, were interviewed for domestic violence, using The Revised Conflict Tactics Scales questionnaire (CTS2).	Of the women, **61.8% (n=247) reported having experienced domestic violence because of their infertility**. Psychological abuse was the commonest form of abuse accounting 33.8% (n =135). This is followed by physical abuse, 14% (n =56), and sexual abuse at 8% (n=32). **Injuries were reported in only 6% of participants (n=24).** In all cases, the husbands were the identified perpetrators of violence. The findings show that domestic violence against infertile women is a major problem that is considerably unreported.
19. Dhont et al	2011	**Mixed methods using quantitative and qualitative methods:**	**Domestic violence, union dissolutions and sexual dysfunction were reported more frequently in the survey by infertile than fertile couples.**

		1. Survey- Couples presenting with female and/or male factor infertility presenting at the infertility clinic in Kigali, Rwanda were asked about domestic violence and sexual functioning. 2. Focus group discussions- Five focus group discussions were held with a subsample of survey participants.	The **psycho-social consequences suffered by infertile couples in Rwanda are severe and similar to those reported in other resource-poor countries**. Although women carry the largest burden of suffering, the negative repercussions of infertility for men, especially at the level of the community, are considerable.
19.	Galhardo et al	2011	**Cross sectional study (N=200):** A study comparing the individual psychological functioning and marital adjustment among normal couples without known fertility problems [NC] (n=80), with, couples with an infertility diagnosis seeking medical treatment [IG] (n=80) and couples with an infertility diagnosis who wish to adopt [AG] (n=40).	Results show that the IG scored higher than NC and AG in measures of depression, external and internal shame. IG also presented higher scores in avoidant and emotional coping styles whereas AG showed higher detached and rational coping. Regarding acceptance and self-compassion, IG showed lower scores in measures of acceptance and self-compassion but scored higher on intimacy than normal controls. **Subjects with an infertility diagnosis showed significant higher scores in psychopathological measures**. There were no differences between the groups were found in terms of sexual functioning.

20. Ogawa et al	2011	**Survey (N=83):** A survey screening for anxiety and depression among patients receiving Assisted Reproductive Treatments (ART) at a reproductive centre in Tokyo, and their association with age, pregnancy and delivery history, employment status, duration of infertility, infertility treatment history, and male infertility.	Total HADS and depression scores increased with increasing age but no correlation was observed. There was **no difference in anxiety or depression scores for patients who had previous deliveries when compared to those who had not.** **Patients undergoing infertility treatment were more likely to have high HADS depression scores** when compared to patients who were yet to undergo treatment **Female patients whose cause of infertility was the male factor had significantly lower total HADS and anxiety scores** than those whose husbands had normal fertility profile.
21. Omosun & Kofoworola	2011	**Cross sectional study (N=350):** A study to determine the knowledge, attitude and practice of child adoption amongst women attending infertility clinics in Lagos, Nigeria.	Results showed 85.7% were aware of child adoption, but only 59.3% of respondent understood what it entailed Majority of respondents (68.3%) testified they could love an adopted child. However, only 33.7% would be willing to consider adoption and 13.9% have a history of adopting a child. Major reason for reluctance to adopt was the desire to have their own biological child.

			Tool: Interviewer administered structured questionnaire.	**According to results of this study, following factors favoured willingness to adopt- Age above 40 years, infertility duration above 15 years and understanding the implication and process of adoption.** Also people of a particular ethnicity in Nigeria (Igbo) seemed more likely to embrace adoption. **Findings suggest a poor attitude towards adoption even amongst infertile couples.**
22.	Roudsari & Allan	2011	**Qualitative research (N=30):** Infertile women of different Islamic and Christianity denominations were interviewed. Semi-structured in-depth interviews were carried out at fertility clinics in the UK and Iran. The Straussian mode of grounded theory was used for data analysis.	Finding showed the following emerging categories: 1. Appraising the meaning of infertility religiously. 2. Applying religious coping strategies. 3. Gaining a faith-based strength. Religious infertile women '*experienced infertility as an enriching experience for spiritual growth'*, which helped them to gain self-confidence and strength to manage their emotions. **Findings suggest the benefits of considering religious and spiritual issues in addition clients' psychosocial needs, by infertility counsellors.**
23.	Adesiyun et al	2012	**Case report**: A case report of a 20-year old orphan (para 0+0),	On examination, it was found to be a fake baby bump made up of a calabash wrapped in her cloth.

			presenting with an 11-month pregnancy, and no prior symptoms of pregnancy.	**Findings showed that the patient resulted to this deliberate event in response to delayed pregnancy complicated by domestic violence in the form of physical and verbal abuse**, precipitated by the onset of her monthly menstrual flow. This case study highlights dilemma of infertility patients in African societies and the associated psychological burden. It shows to what extent disempowered patients will go to avoid the wrath of expectant family members.
24.	Fledderjohan	2012	**Qualitative research (N=107):** Interviews using semi-structured interview collected from seeking treatment in gynaecological and obstetric clinics in Accra, Ghana. .	The focus of analysis of this study was placed on mental health, marital instability, social interaction and gendered experiences The findings showed that the **women experienced severe social stigma, marital conflict and of mental health complications.** Many of the women perceived that they carried a disproportionate share of the blame for infertility. This resulted in bearing more of the social consequences of infertility unlike their male partners for their inability to conceive. This was also the same for women whose inability to conceive was due to male factor causes.
25.	Mascarenhas et al	2012	**Prevalence study (N=277 health surveys):** 277 demographic and reproductive health surveys	In 2010, among women 20–44 y of age who were exposed to the risk of pregnancy, the global prevalence of primary infertility was 1.9% and secondary infertility was 10.5%.

		from 190 countries globally, from 1990 to 2010. Data sets were analysed to determine an algorithm to calculate infertility.	The prevalence of primary infertility was higher among women aged 20–24years (2.7%) in 2010) compared to women aged 25–29 years (2.0%) and women aged 30–44 years (up to 1.7%). Prevalence of secondary infertility increased abruptly with age, from 2.6% in women aged 20–24 years to 27.1% in women aged 40–44 years. **Infertility prevalence was highest in South Asia, Sub-Saharan Africa, North Africa/Middle East, and Central/Eastern Europe and Central Asia.** Due to population growth, however, the absolute number of couples affected by infertility increased from 42.0 million in 1990 to 48.5 million in 2010.
26. Yusuf et al	2012	**Cross-sectional study (N=81):** A descriptive study of correlates of psychological distress among males with infertility in Zaria, Nigeria.	Findings show that 32.1% (n=26) patients scored above the cut-off points of HADS. **Psychological distressed was identified in 28.4% (n=23). Out of these 17.3% (n=23) were found to be depressed while 11.1% (n=9) had a generalised anxiety disorder** Psychological distress was **significantly associated with a history of marital divorce.**

			Thirty-five percent of participants reported a previous history of sexually transmitted infection (STI).
27. El-Kissi et al	2013	**Cross sectional study (N=100 couples):** A gender comparative study of psychological profile in infertile couples to evaluate general psychopathology, depression, anxiety and self-esteem. Tools: Symptom check-list (SCL-90-R), Hospital anxiety and depression scale (HAD-S) and Rosenberg self-esteem scale (RSE).	Infertile women had higher scores than their spouses in the three global scores of the SCL-90-R. Women also scored higher in measures of somatisation, obsessive symptoms, interpersonal sensitivity and phobias. Anxiety and depression was found to be higher amongst women using the HADS scores. Self-esteem values were also found to be lower in women when compared with men. **According to the findings of the study infertility is associated with psychological distress for both women and men. However, women suffered more than men in general psychopathology, anxiety, depression and self-esteem.**
28. Hammarberg & Kirkman.	2013	**Review Article:** This article confronts the idea that infertility is not a serious problem in resource-constrained settings.	**The consequences of infertility can be severe in low income settings**, often resulting in physical and psychological abuse, polygamy and even suicide. In low-income countries, families depend on children for economic survival, thus childlessness and having few children have socioeconomic implications in addition to its medical burden.

			High-income countries and stakeholders trivialise the need for infertility care in low-income countries; more focus is placed upon family planning activities to reduce fertility and control population growth due to scarce healthcare resources within such settings
			The article reinforces the need for infertility care and affordable assisted reproduction treatment, in low resource settings.
29. Abarikwu	2013	**Review Article:** This article analyses data from different sources, presenting an indication of the possible causes and risk factors for male-factor infertility in Nigeria	Recent studies have reported a decline in the semen quality of young healthy men worldwide. **This article highlights the association between impaired semen quality (sperm count, motility as well as morphology), exposures to heavy metals (cadmium and lead), mycotoxins (aflatoxins, pesticides, industrial chemicals), and endocrine factors.** In Nigeria, the problem of poor semen quality and male factor infertility is complicated by factors such as sexually transmitted infections.
30. Wu et al	2013	**Prospective cohort study (N=319 couples):** A cohort study done in California, USA, to determine the time infertile couples spend seeking and utilizing fertility. Couples were	Over an 18-month time period, the average time spent on fertility care was 125 hours (15.6 days, assuming an 8-hour workday). For couples utilizing cycle-based treatments, overall time spent pursuing care averaged 142 hours (provider visits accumulated 73 hours); Couples using other therapies averaged 58 hours.

		followed over an 18 month period.	Multivariable adjustments for clinical and sociodemographic characteristics showed that possessing a college degree and intensity of fertility treatment were independently associated with increased time spent pursuing fertility care. **Couples that spent the most time on care were significantly more likely to experience fertility-related stress**.
31. Rouchou	2013	**Review Article:** A literature review of primary peer reviewed research articles that were conducted from qualitative research using one to one interviews and focus group discussions in Africa, Asia and the Middle East.	The study findings highlight infertility as an ignored, but major public health issue and raises awareness of consequences of infertility in developing countries. **In developing countries, there are severe social, psychological and economic consequences for infertile men and women**. **Education programmes tailored to each society's specific religious beliefs and grounded traditions are required** in order to reverse the social stigma, detrimental psychological effects, and loss of economic security that results from infertility.
32. Momoh et al	2015	**Retrospective cohort study N=63):** A retrospective study to review the seminal fluid analysis (SFA) of couples presenting with inability to	**After analysis, 52.38% had normal SFA.** The World Health Organization 2010 criteria was used as a guideline. Findings showed Azoospermia in 26.98% and Oligospermia 20.64%. Asthenospermia was the commonest motility/morphology abnormality occurring in 60.3%.

		conceive at a gynaecological clinic in Birnin Kudu, Nigeria.	The volume, motility, morphology, and pH showed weak correlations with age.
33. Bokaie et al	2016	**Qualitative study (N=23):** An in-depth semi-structured interview involving 15 women with infertility and 8 key informants made up of health professionals, taking place at Infertility Medical-Research Centre of Yazd, in Iran.	The research findings identified 3 main themes, as perceptions that directly or indirectly affected sexual behaviours in infertile women. They are: 1. Cultural, religious, or ethnic beliefs. 2. Belief in the effect of diet on infertility. 3. Effect of the type of intercourse on getting pregnant. **Lack of awareness about infertility in societies encourages superstitious beliefs**. Societal superstition should be recognized at infertility centres and necessary trainings to alleviate such should be provided by medical staff and reproductive health experts. The author also recommended counselling at infertility centres by reproductive health experts to alleviate unfounded perceptions and educate infertility patients about infertility causes and management.

Appendix 2

Participant Information sheets

INFORMED CONSENT FORM

IRB Research Approval Numbers:

NHA: NHA/EC/035/2014

UCH: UI/EC/17/0061

UoL: 2121

This approval will elapse on:

NHA: 02/03/2017

UCH: 26/03/2018

Title of Research:

Interventions to reduce psychological morbidities associated with infertility in Nigeria: The use of cognitive behavioural therapy based counselling.

Name and affiliations of researcher:

This study is being conducted by:

Dr Abiola Aiyenigba, PhD researcher (Women's Health). Department of Women & Children's Health, Institute of Translational Medicine, University of Liverpool.

Under the Supervision of:

1. Prof Andrew Weeks. Professor of International Maternal Health. University of Liverpool.
2. Prof Atif Rahman. Professor of Psychiatry. University of Liverpool
3. Dr Efena Efetie. Consultant Obstetrics & Gynaecology. National Hospital, Abuja.

4. Dr Charles Aimakhu, University College Hospital. Ibadan, Nigeria.

Sponsors of Research:

University of Liverpool.

Purpose of Research:

The purpose of this research is to test a counselling intervention used to reduce psychological problems as a result of infertility.

Procedure of the Research:

You are invited to take part in a study using counselling to help deal with the stresses of trying to have a baby. This counselling programme is based on a method called Cognitive Behavioural Therapy (CBT). The counselling will take place at regular weekly sessions over a six week period. What CBT simply means is changing negative thoughts and actions into positive ones by the way we think about a problem. This helps to find a suitable, rational solution to the existing problem, thereby improving the state of the mind. Scientific research has shown that improving psychological and mental wellbeing improves reproductive health.

Why is this study important?

According to the World Health Organisation, infertility is when couples are not able to conceive, carry or deliver a healthy baby within 2 years of unprotected intercourse. This occurs commonly to couples in our society; even after previous successful pregnancies and live birth(s), also known as secondary infertility. Childlessness particularly is a major source of stress and stigma for many couples trying to have a baby in African society. Often times the stress associated with infertility cases comes from self-blaming or guilt. At other times, the stress comes from a spouse, family and friends' opinions and expectations. The pressure causes many to become sick with worry making it even more difficult to have a desired pregnancy. Infertility is a major cause of discord within the relationships leading to marital breakdown, domestic violence and infidelity. All these problems add up, making the treatment process even more difficult and challenging.

Counselling, in addition to medical treatment, provides total care. This approach to treatments has been widely used in the treatment of cancer, stroke and HIV. It has also been used to empower women to Safe Motherhood. Having a good understanding and positive attitude helps us to follow proper treatment and make the right choices concerning our health. This is especially important in infertility treatment. A clear mind will help couples to make sensible considered choices about their treatment, rather than just accepting any treatments being offered to them.

We have designed a counselling programme based on CBT to help people deal with the psychological burden while receiving treatment for infertility in Nigeria. The counselling session will provide participants with ways to challenge and change negative thoughts and actions into positive ones. This programme is to be tested and its effectiveness measured in those who consent to participate in the study.

Why have I been invited to take part in this study?

This programme is designed for those currently receiving treatment for infertility at the hospital. You have been invited to take part because you are currently receiving treatment at the University College Hospital, Ibadan.

Do I have to take part?

No, you don't have to take part in this study. Only people who agree to take part will participate. Even if you agree to take part, you have the right to withdraw at any stage for whatever reason. The decision will not affect the care or treatment that you will be receiving at the hospital now or in the future.

What will happen to me if I take part?

There are 3 parts to this study:

Cross-sectional study involving a survey measuring the mental wellbeing of patients undergoing infertility treatment

The pilot clinical trial study of the FELICIA programme which is an infertility counselling programme. One to one interviews (qualitative research) for some of the FELICIA participants.

At the start of the study, we will make sure that you understand what we are going to do and you have given your consent to participate. You will then be given a questionnaire to fill out. In this questionnaire, we will ask questions to assess your mental health and wellbeing with tools, called the GHQ12 questionnaires. The results will be recorded and analysed. If your results show that your wellbeing is being affected, you will be invited to participate in a clinical trial testing a counselling intervention for infertility. The programme, called FELICIA, involves weekly counselling sessions for up to 6 weeks depending on your individual needs. Your clinic nurse, who will be trained to provide you with the CBT based counselling, will help you in making this decision. At the end of your counselling session, we will check your level of wellbeing again to measure if this counselling has been effective for you.

This programme has been designed in cultural sensitive way to meet the psychological needs of patients while undergoing infertility treatments. We would like to hear from you how receiving treatment for infertility has affected you emotionally, and in other ways. We would also like to offer help by providing you ways that can help you deal with negative thoughts, turning them into positive ones.

Furthermore, you might be asked to participate in one to one interviews asking you about what you feel about the session and how useful you considered it to be. Not everyone will take part in this as those who participate will be determined by randomly selection. You will also have the chance to choose whether you want to take part in this. The interviews will be audio recorded and transcribed for analysis. All identifiable data will be kept confidential and separate from the transcribed data. Your privacy and confidentiality will be maintained at all times.

What are the possible risks of taking part in this study?

There are no identified risks. However we are aware that during the discussions, you might become emotionally disturbed having to relate your challenges while seeking treatment for infertility. As this is a counselling session, your health professional is there to help you deal with those issues. It

will be helpful to tell them how you feel. This will help us to understand your situation and help to meet your individual needs.

What are the cost of taking part?

Taking part in this research will not cost you any money. However you will be required to give some of your time to attend counselling sessions once every week. You will be reimbursed for travel expenses outside of your usual clinic visits.

What are the benefits of taking part?

By participating in this study, you will be contributing to research that seeks to provide total care for infertility in Africa. You may have access to methods that help you change negative thoughts and actions into positives ones. This may empower you to make the right decision concerning your health as well as reaching your desired goal.

Will my taking part be confidential?

Yes. We will maintain strict confidentiality at all stages of this study. All personal and identifiable data will be stored away in a locked place. The sessions have been designed to be one to one, which maintains your privacy. However, if you wish to attend with your spouse, you may do so, as long as you both agree that this is your choice.

How is this project funded?

This research is part of a study by Dr Abiola Aiyenigba, who is a PhD researcher at the University of Liverpool. The counselling programme is part funded by the University of Liverpool Global Health Fund. The University College Hospital is working in collaboration with the National Hospital Abuja, here in Nigeria, and Sanyu Research Unit, at the University of Liverpool, UK to support this project.

What will happen to the results of the study?

The findings of the research will be published in a research journal. This will be publicly accessible to all. Your results will be shown in this publication but

will be reported with other participants' results. You will not be individually identified.

Also this programme involves a pilot (trial) study and the result will help develop a larger study to test this approach within a wider population.

2.13: Who should I contact for further information?

For further information, please contact:

1. Dr Abiola Aiyenigba

Email: aiyenigbaabiola@gmail.com

2. Dr Efena Efetie

Email: efenae@yahoo.com

Appendix 3

Informed Consent

INFORMED CONSENT FORM

Title of Research:
Interventions To Reduce Psychological Morbidities Associated With Infertility In Nigeria.

Researcher:
Dr Abiola Aiyenigba, Institute of Translational Medicine. Dept. of Women & Children's Health. University of Liverpool.

Informed Consent

I confirm that I have read and understand the information provided for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and that this will not affect my legal rights. ☐

I understand that any personal information collected during the study will be anonymous and remain confidential. ☐

I agree to take part in the above study which consists of 3 parts:

a) A screening questionnaire to find eligible participants to the trial Y/N
b) Pilot clinical trial if eligible Y/N
c) A qualitative research in form of one to one interviews if eligible Y/N

I understand that the interview in part (c) will be audio recorded and I am happy to proceed. ☐

I understand that parts of our conversation may be used verbatim in future publications or presentations but that such quotes will be anonymized. ☐

Name of Participant Date Signature

Name of Researcher Date Signature

Informed Consent form specifically required by

University College Hospital, Ibadan.

Statement of person obtaining informed consent:

I have fully explained this research to

_____ and I have given sufficient information, including risks and benefits, to make informed decision.

DATE: _____ SIGNATURE: _____

NAME: _____

Statement of person obtaining informed consent:

I have read the description of the research and have had it translated into a language that I understand. I have also discussed with the doctor to my satisfaction. Understand that my participation is voluntary. I know enough about the purpose, methods, risks and benefits of the research to judge that I want to take part in it. I understand that I may freely stop being a part of the study at any time. I have received a copy of this consent form and additional information sheet to keep for myself.

DATE: _____ SIGNATURE: _____

NAME: _____

Appendix 4

Ethical Approval from NHA Nigeria

NATIONAL HOSPITAL

(Established by Act No 36 of 1999).

ABUJA

BOARD CHAIRMAN:
Dr. Tony Okam

DIRECTOR OF ADMINISTRATION
S. U. Gyaranya, B.A (Comb. Hons), AHSAN, MNIM
Member/Sec. to the Board

CHIEF MEDICAL DIRECTOR / CEO
Dr. J. A. F. Momoh, MBBS, MSC, FWACP(LM)

Ag. DIRECTOR OF CLINICAL SERVICES/CMAC
Dr. Ogugua Osi-Ogbu, MB,BS., D.A.B

NHA/ADMIN/236/V.VII/

3rd March, 2015

RE: INTERVENTIONS TO REDUCE PSYCHOLOGICAL MORBIDITIES ASSOCIATED WITH INFERTILIFY IN NIGERIA

HREC Assigned number: NHA/EC/035/2014

Name of Principal Investigator: Dr. Abiola Aiyenigba

Address of Principal Investigator: Institute of Translational Medicine
Department of Women & Children's
Health University of Liverpool, UK

Date of Receipt of Valid Application: 28th November, 2014

Notice of Approval

This is to inform you that the research described in the submitted protocol, the consent forms, advertisements and other participant information materials have been reviewed and *given full approval by the Institute Review Board (IRB) Committee, National Hospital Abuja.*

This approval dates from **3rd March, 2015** to **2nd March, 2017.** If there is delay in starting the research, please inform the HREC National Hospital Abuja so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the HREC assigned number and duration of HREC approval of the study.*

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the HREC. No changes are permitted in the research without prior approval by the HREC except in circumstances outlined in the Code. The HREC reserves the right to conduct compliance visit to your research site without previous notification.

Dr. O. Osi-Ogbu
(Ag. CMAC)
For: Chairman, HREC, National Hospital

Plot 132 Central District (Phase II) P.M.B. 425, Garki - Abuja Nigeria
Telephone: 0803-787-9543, 0809-751-9764, 0809-752-0012
E-mail: info@nationalhospitalabuja.net www.nationalhospitalabuja.net

Ethical Approval from UCH, Ibadan, Nigeria.

INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT)
College of Medicine, University of Ibadan, Ibadan, Nigeria.

Director: **Prof. Catherine O. Falade,** *MBBS (Ib), M.Sc., FMCP, FWACP*
Tel: 0803 326 4593, 0802 360 9151
e-mail: cfalade@comui.edu.ng lillyfunke@yahoo.com

UI/UCH EC Registration Number: **NHREC/05/01/2008a**

NOTICE OF FULL APPROVAL AFTER FULL COMMITTEE REVIEW

Re: Interventions to reduce Psychological Morbidities associated with Infertility in Nigeria: The Use of Cognitive Behavioural Therapy Based Counselling among patients of the University College Hospital, Ibadan, Nigeria

UI/UCH Ethics Committee assigned number: UI/EC/17/0061

Name of Principal Investigator:	**Dr. Abiola Aiyenigba**
Address of Principal Investigator:	Department of Women & Children's Health, Institute of Translational Medicine, University of Liverpool.
Local Supervisor:	**Dr. C. O. Aimakhu**
Date of receipt of valid application:	15/02/2017

Date of meeting when final determination on ethical approval was made: **N/A**

This is to inform you that the research described in the submitted protocol, the consent forms, and other participant information materials have been reviewed and *given full approval by the UI/UCH Ethics Committee.*

This approval dates from **27/03/2017 to 26/03/2018.** If there is delay in starting the research, please inform the UI/UCH Ethics Committee so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the* UI/UCH EC *assigned number and duration of* UI/UCH EC *approval of the study.* It is expected that you submit your annual report as well as an annual request for the project renewal to the UI/UCH EC at least four weeks before the expiration of this approval in order to avoid disruption of your research.

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the UI/UCH EC. *No changes are permitted in the research without prior approval by the* UI/UCH EC *except in circumstances outlined in the Code. The* UI/UCH EC *reserves the right to conduct compliance visit to your research site without previous notification.*

UI/UCH EC APPROVED COLLEGE OF MEDICINE

Professor Catherine O. Falade
Director, IAMRAT
Chairperson, UI/UCH Ethics Committee
E-mail: uiuchec@gmail.com

Ethical Approval from University of Liverpool.

UNIVERSITY OF LIVERPOOL

Research Integrity and Ethics

4 July 2017

Dear Prof Weeks,

We are pleased to inform you that your application for research ethics approval has been approved. Details and conditions of the approval can be found below:

Reference:	2121
Project Title:	Interventions to Reduce Psychological Morbidities Associated with Infertility in Nigeria
Principal Investigator/Supervisor:	Prof Andrew Weeks
Co-investigator(s):	Dr Abiola Ayenigba
Lead Student Investigator:	-
Department:	Women's and Children's Health
Approval Date:	04/07/2017
Approval Expiry Date:	Five years from the approval date listed above

The application was APPROVED subject to the following conditions:

Conditions

- All serious adverse events must be reported via the Research Integrity and Ethics Team (ethics@liverpool.ac.uk) within 24 hours of their occurrence.
- If you wish to extend the duration of the study beyond the research ethics approval expiry date listed above, a new application should be submitted.
- If you wish to make an amendment to the research, please create and submit an amendment form using the research ethics system.
- If the named Principal Investigator or Supervisor leaves the employment of the University during the course of this approval, the approval will lapse. Therefore it will be necessary to create and submit an amendment form using the research ethics system.
- It is the responsibility of the Principal Investigator/Supervisor to inform all the investigators of the terms of the approval.

Kind regards,

Research Integrity and Ethics

0151-794-8290

0151-795-8355

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Appendix 5

Tools for Data Collection

Questionnaires for Cross-sectional survey at NHA and UCH.

Cross sectional Survey Questionnaire: The psychological morbidities associated with infertility in Nigeria

Thank you for taking time to complete this questionnaire. Please read the questions carefully and answer as honestly as you can.

Circle the answer(s) that apply to you the most. The findings of this survey will give us information on how to provide better care for you and other people going through infertility treatments. Please be assured that all information given remains strictly confidential at all times.

Please note it is important to fill in all parts of the questionnaire, where applicable. Thank you.

For Further enquiries please contact: Dr Abiola Aiyenigba
Email: aiyenigbaabiola@gmail.com

A: ABOUT YOU:

1. **What is your gender?**
   Male Female
2. **How old are you on your next birthday (in years)?**
   25 or less 26-30 31-35 over 35
3. **Are you married?**
   Yes No Separated/Divorced
4. **If married, how would you describe the type of your marriage?**
   Monogamy Polygamy Not Applicable
5. **Do you have other sexual partners outside of your primary relationship? (**Applies also to unmarried participants)***
   Never Yes, previously. Yes, within last 6 months
6. **How many live children do you have?**
   0 1 2-4 5
7. **What is the level of your education (current or completed)?**
   Primary Secondary Higher Education
8. **What is your current employment status?**
   Employed Self-employed Unemployed

B: ABOUT YOUR INFERTILITY TREATMENT:

1. **What type of infertility are you being treated for?**
   Primary Secondary Male Unknown
2. **How long have you seeking treatment for infertility?**
   0-2yrs 3-5yrs >5yrs
3. **Have you ever had a miscarriage (spontaneous abortion)? If yes, how many?**
   Never 1 2 3 or more
4. **Have you ever had an abortion as a result of unwanted pregnancy? If yes how many?**
   Never 1 2 3 or more
5. **At what stage of infertility treatment are you, currently?**
   A. Initial referral to fertility specialist
   B. Diagnostic tests and procedures
   C. Definitive diagnosis, awaiting treatment
   D. 1 cycle of treatment completed
   E. 2 cycles of treatment completed
   F. 3 cycles of treatment completed
   G. 4 or more cycles of treatment
   H. Treatments stopped.
6. **How many times have you been pregnant? Please specify. _____**

C: ABOUT YOUR RELATIONSHIP:

1. **Do you feel supported by**
   Spouse: Always Never Sometimes
   In-laws: Always Never Sometimes
   Friends: Always Never Sometimes
2. **Have you ever suffered physical or verbal abuse as a result of your infertility problems? (Tick all that apply)**
   Never. Yes, currently. Yes, in a previous relationship.
3. **Do you suffer verbal or physical abuse from any friends or family due to infertility problems within the last 6 months? (Tick all That apply)**
   Never Spouse In-laws Friends Other people
4. **Have you experienced divorce or breakdown of a relationship as a result of infertility problems?**
   None 1 2 3 or more

5. Who carries responsibility for treatment costs? (Tick all that contribute)

Myself My partner Other

D: ABOUT YOUR GENERAL HEALTH & WELLBEING (Goldberg, 1978)[1]

HAVE YOU RECENTLY…

1. Been able to concentrate on what you're doing?

0.Better than usual 1.Same as usual 2.Less than usual 3.Much less than usual

2. Lost much sleep over worry?

0.Not at all 1.No more than usual 2.Rather more than usual 3.Much more less than usual

3. Felt that you are playing a useful part in things?

0.More so than usual 1.Same as usual 2.Less so than usual 3.Much less than usual

4. Felt capable of making decisions about things?

0.More so than usual 1.Same as usual 2.Less so than usual 3.Much less than usual

5. Felt constantly under strain?

0.Not at all 1.No more than usual 2.Rather more than usual 3.Much more less than usual

6. Felt you couldn't overcome your difficulties?

0.Not at all 1.No more than usual 2.Rather more than usual 3.Much more less than usual

7. Been able to enjoy your normal day to day activities?

0.More so than usual 1.Same as usual 2.Less so than usual 3.Much less than usual

8. Been able to face up to your problems?

0.More so than usual 1.Same as usual 2.Less so than usual 3.Much less than usual

9. Been feeling unhappy or depressed?

0.Not at all 1.No more than usual 2.Rather more than usual 3.Much more less than usual

10. Been losing confidence in yourself?

0.Not at all 1.No more than usual 2.Rather more than usual 3.Much more less than usual

11. Been thinking of yourself as a worthless person?

0.Not at all 1.No more than usual 2.Rather more than usual 3.Much more less than usual

12. Been feeling reasonably happy, all things considered?

0.More so than usual 1.Same as usual 2.Less so than usual 3.Much less than usual

[1] 12 Item General Health Questionnaire - GHQ12 (Goldberg, 1978)

Semi Structured Interview questions for Qualitative Research at UCH Ibadan.

Question No	Questions asked.
1	What do you think about the FELICIA counselling programme overall? Can you give practical examples about your experiences?
2	Did you find this counselling programme useful to you? If yes, why and how? (Please give examples) If No, why/why not?(Please give examples)
3	Did you feel empowered after participating in the intervention? Why or why not? (Please give practical examples of your experiences)
4	If you could change anything about this programme method, what would that (or these) be? Why would you prefer to see these changes?
5	Would you recommend the FELICIA programme to other people in the same situation as yourself? Why/Why not?

Appendix 6

Information about FELICIA manual

The Fertility Life Counselling Aid (FELICIA) is available via open access at:

https://doi.org/10.6084/m9.figshare.6729110.v1

A CD copy is also available.